SMALLPOX VACCINE CONTROVERSY GROWS — PAGE 4

Trust Medicare to Manage Rx Drugs? PAGE 10

Health Care News

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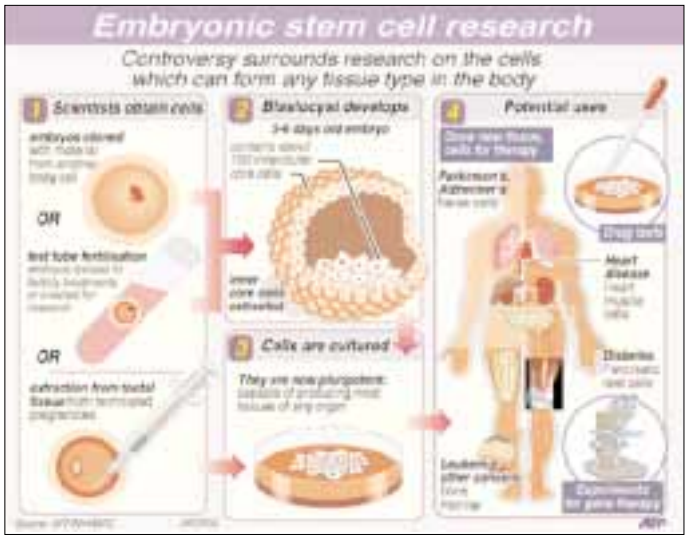
California Defies Federal Stem Cell Policy



BY DIANE CAROL BAST
AND CONRAD F. MEIER

On September 22, California Gov. Gray Davis signed into law a bill that encourages stem cell research using embryos from fertility clinics or embryonic cloning. The measure takes effect January 1, 2003.

The move puts California directly at odds with federal government policy, outlined by President George W. Bush in August 2001, which allows federally funded scientists to conduct their research only with 78 existing stem cell lines. (For background on the debate, see "Bush Takes Center Field on Stem Cell Funding Issue," *Health Care News*, September 2001.)

California Senate Bill 253 was introduced by State Senator Deborah V. Ortiz (D-Sacramento), whose mother died of ovarian cancer in 1999. "I have a commitment to cancer research," Ortiz told ABCNEWS.com. "California will protect science and research while the rest of the country is still questioning."

Enlisting Fertilization Clinics

Ortiz's measure declares "that the policy of the state shall be that research involving the derivation and use of human embryonic stem cells, human embryonic germ cells, and human adult stem cells from any source" shall be permitted.

To give the new policy teeth, the California law requires in vitro fertilization clinics to inform patients that they have several options for the disposition of any human embryos left over after the fertility treatment. Those options, outlined in the law, include "storing any unused embryos, donating them to another individual, discarding the embryos, or donating the remaining embryos for research." Clinics are required to get written consent from any patient who elects to donate embryos for research.

The measure forbids the sale of embryonic cells for profit and establishes a state ethics committee to review and approve any research

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Britain Reconsiders Private Health Care

BY DR. DAVID G. GREEN

Managing Editor's Note: David Green, director of London's CIVITAS, The Institute for the Study of Civil Society, sees progress in the debate over opening England's single-payer health care system to private players, competition, and choice.

The Government is rigidly opposed to any change in the way we finance health care. We will have no "American-style system here," Tony Blair declared in a recent major speech. But, off-camera, radical changes in the method of delivering care are being contemplated.

Secretary of State for Health, Alan Milburn, has been advocating the de-politicisation of hospitals. In public, he insists it is not privatisation, but in off-the-record meetings he has been saying he is not worried whether policy wonks categorise hospitals as "public sector" or "private sector."

The real challenge is to preserve an ethos of public service. Even on public occasions (such as his speech to the New Health Network), Mr. Milburn admits the search is on for a "middle ground between state-run public and shareholder-led private structures."

For too long the debate has been dominated by a false polarisation between "public" and "private." There are many ways of fostering a public service ethos in the private sector and, at last, the debate is no longer about whether or not to depoliticise, but about which non-government structures work best. Mr. Milburn specifically mentioned mutuals and non-profit companies as forms of private activity now considered palatable by Labour.

One idea under active consideration is for three-

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AIDS Activists Hinder Their Cause

BY ROGER BATE

In September at the World Summit on Sustainable Development, the head of UNAIDS, Peter Piot, told delegates he was upset that AIDS discussions were not higher up the agenda of the summit. He will be even more upset when he sees the latest data about AIDS research.

There are between 5 and 30 percent fewer anti-AIDS drugs in development than there were a few years ago. A UK government commission would further reduce the number of AIDS drugs in development if its recommendations are followed.

PharmaProjects is an independent consultancy, employed by the pharmaceutical industry to survey companies working on all forms of anti-infective drugs.

The consultancy found that the overall trend in drug development is slightly upwards, roughly 5 percent more anti-infectives in development than in 1998. But the overall increase was lower than had been expected and hides an interesting, but worrying, trend in one sector of the market, which pulled down the average.

Companies producing anti-AIDS drugs were developing fewer products than in the late 1990s—almost one-third fewer in 2001 than in 1998.

Some industry representatives are skeptical the reduction is as substantial as one-third, and

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Bush Picks His Man

BY CONRAD F. MEIER

After a long delay, President George W. Bush on September 25 nominated Dr. Mark McClellan, a senior White House health policy advisor, to serve as commissioner of the Food and Drug Administration (FDA).

Currently, McClellan is a member of the White House Council of Economic Advisors. Before joining the Bush administration, he was an associate professor of both economics and medicine at Stanford University. McClellan has a degree in medicine from Harvard Medical School and a Ph.D. in economics from MIT.

McClellan has represented the Bush administration on several controversial health care issues, including Medicare prescription drug benefit proposals and the "giveback" bill for health care providers.

As FDA commissioner, McClellan would face a number of major issues. For example, the pharmaceutical industry and patient advocacy groups have asked for more expedited reviews of new drug-based treatments, as consumer advocates lobby for a more cautious approach.

McClellan also would step into a thorny free-speech issue. The FDA has begun to review restrictions on commercial speech in areas such as television advertisements for prescription drugs and food labels.

Support Is There

White House spokesperson Scott McClellan, the nominee's brother, said Mark McClellan would continue in his current role at the Council of Economic Advisors during the confirmation process. Although analysts expect the Senate to approve McClellan's nomination, it is unlikely he would receive confirmation before the end of the congressional session.

McClellan's primary expertise is in the economics of health care. Some industry spokesmen welcomed his nomination. "We are pleased that the Bush administration has made a selection to fill this critical position, and from Dr. McClellan's educational background and experience in medicine, health care, and economic policy, he appears to be an excellent candidate," Biotechnology Industry Organization President Carl B. Feldbaum said.

The Pharmaceutical Research and Manufacturers of America (PhRMA) expressed pleasure that the White House had finally selected a candidate, but also said it needs to learn more about McClellan and his career before commenting on his suitability for the position.

President George W. Bush (right) welcomes to the Oval Office Dr. Mark McClellan, who the President has nominated as commissioner of the Food and Drug Administration. *photo:Tim Sloan*

Although McClellan's nomination has received positive nods from industries regulated by the FDA, consumer advocacy groups like Public Citizen have questioned his management and scientific experience.

> **"After a long delay, President George W. Bush nominated Dr. Mark McClellan, a senior White House health policy advisor, to serve as commissioner of the Food and Drug Administration (FDA)."**

Peter Lurie, deputy director of the Health Research Group at Public Citizen, told *USA Today* McClellan has expertise in the use of medical treatments, an area "not directly relevant to the FDA's responsibilities."

Grace-Marie Turner, president of The Galen Institute, disagreed with Lurie's take on the nominee. "There aren't enough superlatives to describe how invaluable Mark has been to shaping the Bush administration's free-market agenda during less than 20 months as the President's chief health policy advisor and member of his Council of Economic Advisors," she said.

Turner also noted the evidence indicates McClellan quickly masters any task he tackles. "Mark put into policy language the President's broad vision of a patient-centered health system that combines high quality with universal accessibility. His prior research into the value and costs of new technologies will be particularly relevant at the FDA," she said.

An article in *The Washington Post* quoted Sen. Edward Kennedy (D-Massachusetts), chair of the Senate Health, Labor, Education and Pensions Committee, as saying McClellan has "impressive credentials both as a physician and as an economist." Senator Judd Gregg (R-New Hampshire) called McClellan "a thoughtful and conscientious choice."

McClellan's Replacement

In related news, Health and Human Services (HHS) Assistant Secretary for Planning and Evaluation Bobby Jindal has emerged as the leading candidate to replace McClellan at the Council of Economic Advisors.

In his position at HHS, Jindal has worked with the White House on health care legislation, strategic planning, and regulatory reviews. In the past, Jindal served as secretary of the Louisiana Department of Health and Hospitals and as executive director of a 1998-99 federal advisory commission that recommended broad Medicare reforms.

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The PULSE

BY GREG SCANDLEN

FREE-MARKET HEALTH CARE REFORM IN THE NEWS

Let's rev up those engines by starting with a bit of hubris from academia.

Grant Reeher is a poli-sci professor at the Maxwell School at Syracuse. He begins an article in the *Ottawa Citizen* by saying an Environics poll showed "a genuine state of crisis in U.S. health care is on the way."

He cites four trends:

- the predominance of managed care
- the aging population
- failure to control costs
- failure to guarantee access to care.

He concludes, "These trends will lead to a political environment in the U.S. that favors a major public-sector-based reform of health care policy," probably involving "a government-led effort to coordinate the system, control costs, and expand health care access."

Yes, indeedy. The government has been doing such a swell job with Medicare and Medicaid that Americans are eager to entrust it to run the whole shebang.

Demonstrating how out-of-touch academics really are, Reeher adds, "There has been little creative leadership in the business sector on rethinking health care, where most of the focus has been simply on cutting. The new movement toward 'defined contribution' is only the latest example."

The article includes a sidebar about a survey conducted by Reeher's own Maxwell School, which finds 67 percent of Canadians and 63 percent of Americans think their own health care system is in crisis—hardly an endorsement of government control.

Source: The article ran on September 23, 2002. The paper's archives are supposed to be available for 14 days, but I couldn't find it. Try http://www.canada.com/ottawa/ottawacitizen/

Seattle Docs Dropping Out of Medicare

The *Seattle Times* reports local physicians are less likely to accept new Medicare patients than physicians in other areas of the country. Reporter Carol Ostrom writes, "In 2001, only 54.5 percent of doctors around Seattle accepted new Medicare patients, down from 71.3 percent in 1997."

The article is based on a survey conducted by the Center for Studying Health Systems Change (HSC) of 12,000 physicians around the country. The survey also found that fewer than 8 percent of Medicare patients in Seattle reported having trouble receiving services—half the rate of cities like Cleveland, Miami, and Phoenix. The article cites Tom Curry of the Washington State Medical Association as noting the survey was conducted before the 5.4 percent Medicare cuts in physician payments kicked in.

Source: http://seattletimes.nwsource.com/html/localnews/134530328_medicare06m.html

Medicare Spending Not What You Think

The National Center for Policy Analysis (NCPA) released a couple of *Brief Analyses* on Medicare spending last month. Both written by Andrew Rettenmaier and Zijun Wang of Texas A&M University, the papers reveal some counter-intuitive information about Medicare spending.

The first finds that men on Medicare actually cost more than women do, after adjusting for age. It also finds that racial disparities in Medicare spending have reversed over the past 25 years. In 1974, Medicare spent more on white males than on black males ($1,398 vs. $1,236), while in 1997 Medicare spent $4,372 per white male and $5,452 per black male.

The second paper calls into question the assumption that much of the increase in Medicare spending is attributable to end-of-life care. The authors find that, while it is true the last two years of life are very expensive, they are not becoming more expensive relative to spending on non-terminal patients. Rettenmaier and Wang also find that terminal care for older patients (age 80 and above) is considerably less expensive than terminal care for patients at ages 65 to 69.

Source: http://www.ncpa.org/pub/ba/ba408 *and* http://www.ncpa.org/pub/ba/ba409

Drugs in Canada Cheaper Because Canadians Are Poorer

The Fraser Institute finds the price difference for prescription drugs between the U.S. and Canada is growing, but not for the reasons most people suppose.

An article by John Graham in the *Fraser Forum* finds Canada's Patented Medicine Prices Review Board "is not a significant cause of the 'cheapness' of Canadian patented drugs.

"Canadian health-related goods and services in general are almost as cheap relative to those in the United States as patented drugs are, despite the lack of explicit price controls for them." Why should this be? Because Canadians are getting poorer compared to Americans. Graham says in 1997 the per-capita GDP for the U.S. was 46 percent greater than Canada's, but grew to 55 percent greater in 2001. Drugs sold in Canada, like cars sold in Canada, are cheaper because Canadians can't afford to pay more for them.

Source: http://www.fraserinstitute.ca. *Search for author John Graham.*

HHS Reports Americans Are Healthier than Ever

Not only are Americans getting wealthier, we are also getting healthier, according to a new report from HHS.

In 2000, Americans had the longest life expectancy in our history: 77 years for women and 74 years for men. During the last 50 years, the death rate for children and young adults was cut in half.

Infant mortality alone has dropped 75 percent since 1950. The homicide rates for black and Hispanic males dropped almost 50 percent in the 1990s. More surgeries are being done on an outpatient basis (63 percent of all surgeries in 2000 vs. 16 percent in 1980), and lengths of stays for inpatient surgeries have dropped from more than seven days in 1980 to 4.9 in 2000. Still, fitness remains a concern, as Americans become more obese and more sedentary.

"In 2000, Americans had the longest life expectancy in our history: 77 years for women and 74 years for men. ... The homicide rates for black and Hispanic males dropped almost 50 percent in the 1990s."

Source: The HHS information is at http://www.hhs.gov/news. *The report itself can be found at* http://www.cdc.gov/nchs.

Mandates in Texas Raise Premiums 17 Percent

The *San Antonio Business Journal* attributes premium hikes in Texas in part to mandated benefits. The article cites the Texas Association of Business (TAB) as identifying five of the 63 mandates in Texas as responsible for a 17 percent increase in premiums in that state.

That is why TAB opposes the Mental Health Parity mandate under consideration in Texas. But advocates for the bill claim costs will be higher if mental illness is left untreated, especially through absenteeism, lost productivity, and physical manifestations of mental illness. The article gives an example of one local company that concedes mental health treatment is important, and offers benefits that are near-parity. But this company charges a slightly higher co-payment for mental health treatment, because it wants to continue paying 100 percent of the premium for its workers. It fears some employees would not accept the coverage if they had to pay part of the premium.

Source: http://sanantonio.bizjournals.com/sanantonio/stories/2002/09/02/focus1.html

Greg Scandlen is senior fellow in health policy at the National Center for Policy Analysis in Dallas, Texas and assistant editor for Health Care News. *To sign up for his free weekly e-newsletter,* Scandlen's Health Policy Comments, *log on to* http://www.ncpa.org/sub. *Email Scandlen at* GMScan@aol.com.

You are invited to participate in an online discussion list dealing with many of the issues we report on here. To check it out, send an e-mail to ***HealthBenefitsReform-subscribe@yahoogroups.com****. Later on, if you want to drop off, just send an e-mail to* ***HealthBenefitsReform-unsubscribe@yahoogroups.com****.*

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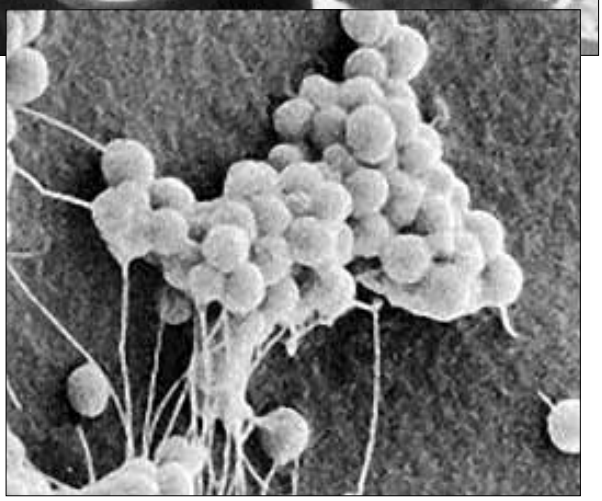
Smallpox Vaccine Controversy Grows

Administration considers making "pre-attack" smallpox vaccinations available to general public



"[I]n early October, sources in the Bush administration said the vaccine could be made available to the general public in a matter of weeks, though more likely it would be released in stages and not reach the general public, absent an outbreak of the disease, until early 2004."

BY JOSEPH BAST

The Bush administration is about to announce a major shift in policy regarding vaccinating the general population against smallpox in case of a terrorist attack. The new policy could make the vaccine available to every American, not only health workers, in advance of a terrorist attack.

Smallpox, along with anthrax, plague, and botulism, is a deadly virus experts believe could be used as a weapon of mass destruction by terrorists. The last case of smallpox in the U.S. was diagnosed in 1971, and routine smallpox vaccination stopped in the U.S. in 1972. Smallpox is estimated to be fatal to one-third of unvaccinated individuals exposed to the virus. (See "Smallpox Health Facts," page 5.)

An Evolving Policy

Shortly after the terrorist attacks of September 11, 2001, government sources reported only 15.4 million doses of smallpox vaccine, made in the 1970s, were available. Researchers soon discovered the doses would still be effective if diluted to one-fifth their current strength. Diluting the vaccine would yield approximately 77 million doses, still too few to immunize the entire country.

In March 2002, however, it was revealed that 86 million doses of an identical vaccine created in the 1950s were being stored by Aventis Pasteur in a freezer in Pennsylvania. Preliminary tests on that supply suggest it is still effective, but it could take two years or longer before the drugs are licensed for use by the Food and Drug Administration. Health officials at the Centers for Disease Control and Prevention (CDC) say they favor waiting until the drugs are licensed. If diluted, the Aventis supply would yield 430 million doses.

The Department of Health and Human Services has signed or expanded contracts for 209 million new doses of the vaccine, which are expected to arrive early next year. Seventy million doses are expected to be on hand by the end of the year.

In June, the national Advisory Committee on Immunization Practices, a government advisory committee, recommended inoculating approximately 15,000 health workers in designated hospitals and facilities. That number has since grown to approximately 500,000 people.

Public support for a faster and more broad vaccination program has grown as word spread of the expanded availability of the vaccine. In early August, Bill Frist, a heart surgeon and Republican senator from Tennessee, penned an influential essay for *The New York Times* saying "we should allow every American to make an informed choice as to whether to be vaccinated. We should immediately vaccinate all military personnel at a high risk of exposure, and allow voluntary vaccinations for those at lower risk."

On September 23, federal officials sent states guidelines for rapidly vaccinating the general population. Such mass immunization was apparently not thought necessary or likely just a few months ago. Then, in early October, sources in the Bush administration said the vaccine could be made available to the general public in a matter of weeks, though more likely it would be released in stages and not reach the general public, absent an outbreak of the disease, until early 2004.

Opposition to Mass Vaccination

The American Academy of Pediatrics opposes mass vaccination before or even after a terrorist attack. Instead, it advocates "ring vaccination," vaccinating only those people who have contact with infected patients, then persons who may have come in contact with those persons, and so on. "That's the model for the successful eradication of smallpox throughout the world," says Dr. Robert Baltimore, a member of the American Academy of Pediatrics' Committee on Infectious Diseases. "Ring vaccination is how smallpox became a disease of the past."

"[The Association of American Physicians and Surgeons] supports making immunizations available 'with full disclosure and informed consent, to those who want them.'"

The CDC also supports ring vaccination, as well as preparations for mass vaccinations in case of a major outbreak.

Elizabeth Whelan, president of the American Council on Science and Health, called the administration's plans to make the vaccine available to the general public in advance of an actual terrorist act "astonishing" and "dramatic."

In an October 3 *Wall Street Journal* essay, Whelan said the administration's new policy will lead "millions of Americans [to] venture into what is basically a large, uncontrolled experiment." She poses a long list of questions she says cannot yet be answered, including how does one make an informed decision about whether or not to be vaccinated? In case of adverse effects from the vaccine, who would be liable? And do recently vaccinated individuals pose a threat to unvaccinated individuals at home or at work?

Whelan advocated "assured access to the vaccine only after it was confirmed that smallpox was indeed available as a terror weapon or even after exposure to smallpox had occurred."

Support for the New Policy

Other experts strongly endorsed the administration's new policy.

"If the news reports are accurate, we're thrilled," says Jane M. Orient, M.D., executive director of the Association of American Physicians and Surgeons. Withholding the vaccine, according to an open letter to President Bush from Orient, "could cost thousands of lives in the event of an outbreak. The plan announced by the CDC to withhold smallpox vaccine until after an outbreak is fatally flawed, and would most likely lead to chaos and thousands of preventable deaths."

Orient's organization supports making immunizations available "with full disclosure and informed consent, to those who want them." In the past the organization has been vocal in opposing mandatory vaccinations.

"It's a fantasy to believe that the control of small natural outbreaks provides guidance for large bioterrorist attacks," Edward Kaplan, a health analyst at Yale, told *Newsweek*. Terrorists could target airports or other transportation hubs, and by the time exposed persons began showing symptoms, they would be scattered across the country, making mass vaccination necessary.

Debate over Safety

Two issues are at the center of the controversy.

SMALLPOX continued on next page

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Smallpox Health Facts

- Smallpox spreads from person to person, primarily via droplets or aerosols expelled from the throat of infected persons, by direct contact, and via contaminated clothing and bed linens. It is fatal in perhaps a third of previously unvaccinated victims.
- Smallpox virus no longer occurs in nature, but is limited to two legitimate repositories, one in the United States, the other in Russia (and perhaps illegitimately in a very small number of other countries). It is, therefore, very difficult to obtain, and also to cultivate and disseminate.
- Smallpox is not immediately contagious. It becomes contagious only after an incubation period and appearance of the characteristic rash, by which time the victim is prostrate, bedridden, and probably hospitalized. Therefore, the scenario in which a terrorist infects himself and spreads the disease widely through the population is not a realistic one.
- Although smallpox vaccination in the United States ended in 1972, individuals who were vaccinated prior to that time retain significant immunity as a result of these immunizations, both against contracting smallpox and against a fatal outcome in case of infection.
- Public health authorities have at their disposal various proven epidemiologic and medical interventions. Early detection, quarantine of infected individuals, surveillance of contacts, and focused, aggressive vaccination—an approach dubbed "quarantine-ring vaccination"—are the essential elements of a control regime.
- The government has taken steps to cope with the possibility of a terrorist attack involving smallpox by educating doctors to recognize the disease and by vaccinating small teams of experts who can rush to any part of the country to contain and treat a suspected outbreak.

Source: Henry I. Miller and Sherri Ferris, "Bioterrorism, Anxiety, and the New Normalcy," American Council on Science and Health, November 15, 2001. **www.acsh.org**.

SMALLPOX continued

First is the risk to health posed by the smallpox vaccine itself. According to data from the 1960s, when the vaccine was last used, approximately 15 out of every million people taking the vaccine will experience life-threatening side effects, and between one and two are likely to die from the effects. If 300 million people are immunized, approximately 350 people could die from complications. Particularly vulnerable are the elderly, the very young, pregnant women, and people with weak immune systems.

Recently immunized people, who carry a live virus called vaccinia, pose a threat to vulnerable unvaccinated people around them. "Anybody who comes in contact with a person who's been vaccinated could be inadvertently infected with the vaccinia virus," according to Baltimore. "If, say, you choose not to be immunized, but people around you are immunized, there is a concern that the virus could spread to you."

This poses a special problem when medical personnel and first responders are vaccinated, since they cannot then come in contact with patients while they are contagious, which can last two weeks. Orient says the CDC believes at least 1.3 million volunteers will be needed to administer the vaccine.

Orient says other vaccines pose a greater threat and yet are widely used, pointing to the hepatitis B vaccine that has caused 440 deaths with only 20 million doses. Others say medical advances during the 40 years since the smallpox virus was last widely used could greatly reduce the death rate, though too little is known about how the disease reacts to modern medicines to be sure.

The second health issue is whether immunizing the general public can wait until after a terrorist attack using the smallpox virus is confirmed. While the vaccine is effective even if taken a few days after exposure, Orient says it will take up to a week for the vaccine to be distributed from national stockpiles, and then another 10 days to deliver 1 million doses. "Massive outbreaks in several population centers could mean a delay of up to a month to receive the vaccine, well after the window of opportunity to use the vaccine as a palliative."

Frist concluded his *New York Times* essay saying "I believe the threat of a smallpox attack outweighs the risks of providing smallpox vaccinations to a well-informed public. Along with the phased-in vaccination of military personnel and first responders, every American should be given this option. Such a policy is a sensible public health response that would enhance our national security."

Joseph Bast is president of The Heartland Institute, the publisher of Health Care News.

Addicted to Tobacco Taxes

Reform process characterized by fits, starts, and small steps in the right direction

BY ROBERT A. LEVY

Arizona's politicians can't make up their minds about tobacco.

When Arizona sued the cigarette makers in 1996, the state minced no words in describing the pernicious effects of smoking: "Tobacco products are not only addictive, they are abnormally dangerous and unfit for human use. Tobacco products kill, maim, and injure virtually all who use them."

Reading that, any rational person would have to conclude the state would criminalize cigarettes. Evidently, consistency and logic take a back seat when big bucks are at stake.

Instead, the "cash-cow" coalition signed a national settlement that protected the profits of the tobacco giants so they can be milked periodically to replenish depleted state coffers.

Now that same coalition is promoting Proposition 303, a statewide referendum on the November ballot to increase Arizona's cigarette tax from 58 cents to $1.18 per pack—the nation's fifth highest rate. The goal of 303 is to pay for a laundry list of programs, like expanded health insurance and funding for trauma centers. Those programs, desirable or not, are mostly unrelated to tobacco prevention.

If taxpayers want more health insurance and trauma centers, let all the taxpayers—not just smokers—foot the bill. Indeed, cigarette surcharges are brutally regressive. They represent a wealth transfer from generally poor smokers to more affluent non-smokers.

Roughly 60 percent of tobacco taxes are paid by smokers with annual incomes under $40,000. Furthermore, federal and state cigarette taxes already generate far more than smoking-related costs paid out of the public purse. The contrast between tax receipts and public costs is mind-boggling.

In 1995, Arizona's excise taxes were 58 cents per pack. According to Harvard economist Kip Viscusi, the state spent 1.12 cents per pack on tobacco-related medical care, and lost 1.55 cents per pack in payroll taxes due to smokers' early mortality.

Thus, the 58 cents per pack excise tax was more than 20 times the combined tobacco-related cost to the state of 2.67 cents. In short, smokers have more than paid their way.

That's Not All

If Proposition 303 passes, the unavoidable consequence will be a flourishing and pervasive black market that spawns illegal dealings dominated by criminal gangs. And who knows where that black market money may end up? In 2000, federal agents arrested 18 Hizbollah guerrillas in North Carolina and Michigan for trafficking in contraband cigarettes to raise funds for Islamic terrorists.

Of course, Tempe, Arizona property owners already know what it's like to be "Propositioned" by the anti-smoking crowd. In May, Tempe voters enacted Proposition 200, which banned smoking in so-called public places, like private restaurants, bars, billiard halls, and bowling alleys.

The ban made Tempe's smokers second-class citizens, despite considerable dispute within the scientific community regarding the link between environmental tobacco smoke (ETS) and adverse health effects.

In an important respect the scientific debate over ETS is beside the point. The real issue is property rights. On private property, only the owner has the right to say how that property is used, providing he respects the valid rights of others.

"Smokers have no legitimate right to light up in my restaurant. Nor do non-smokers have a legitimate right to prevent smokers from lighting up in my restaurant."

Smokers have no legitimate right to light up in my restaurant. Nor do non-smokers have a legitimate right to prevent smokers from lighting up in my restaurant. If I choose to permit smoking, or to prohibit smoking—for good reasons, bad reasons, or no reason at all—that's my business. Smokers or non-smokers who disagree with my decision may go elsewhere.

Prior to Proposition 200, some restaurants in Tempe voluntarily opted for a smoke-free environment, and others offered both smoking and non-smoking sections. Mostly, customers relied on common courtesy and mutual respect to resolve disputes. But thanks to the ban, government has poisoned the atmosphere far more than secondhand smoke ever did. Meanwhile, some Tempe businesses complain their revenue has dropped by as much as 20 percent.

However unpopular the tobacco industry, however repugnant that some people may become addicted to smoking, there are countervailing values that sustain a free society. When government makes unwanted choices for individuals about their recreation, lifestyle, and health, that's paternalism at its worst.

Robert A. Levy is senior fellow in constitutional studies at the Cato Institute. He is the author of a Goldwater Institute policy paper on tobacco issues, released in early October. This op-ed appeared in the September 19 issue of the Arizona Republic.

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STEM CELLS continued from page 1

that uses embryonic stem cells. A separate measure signed by Davis on September 23, Senate Bill 1230, outlaws human cloning and the purchase and sale of embryos and fetuses for the purpose of human cloning.

Symbolic Victory Only?

Leading researchers in the field downplayed California's move as mostly symbolic ... though welcome.

"We certainly appreciate the intent," said Thomas B. Okarma, MD, PhD, president of Geron Corp., a Menlo Park, California biopharmaceutical firm. "But it's not clear whether it will translate into funding, or programs, or real work."

"On September 22, California Gov. Gray Davis signed into law a bill that encourages stem cell research using embryos from fertility clinics or embryonic cloning."

That's because the Bush administration policy still trumps California law when it comes to federally funded researchers ... and the federal government provides roughly 90 percent of research funding in the U.S. Curt Civin, a stem cell researcher at Johns Hopkins University, considers the California law "important as a statement," but essentially a "hollow victory."

GRAY DAVIS DEBORAH ORTIZ

The California bill does promise state funding and matching funds from private biotech companies. The state's biomedical industry boasts 2,500 companies that invest more than $2.1 billion every year in research. Moreover, according to Susanne Huttner, associate vice provost for research at the University of California, the state budget has $24.6 million to allocate for stem cell research. Last year, she said, the state's university system received no proposals for stem cell research, even though there was money available. Since the governor signed SB 253 proposals have started coming in.

Dr. Bertram Lubin, MD, senior vice president for research at Children's Hospital & Research Institute at Oakland University, predicted most researchers would "tread lightly on this for a while," fearful that accepting California research funds under the new law might jeopardize their federal funding. He nevertheless appreciated the measure's political potential, noting "California may push the federal government to change its policies."

States' Rights

When asked for the President's reaction to California's action, White House press secretary Ari Fleischer called it a matter of "states' rights." "The President has always said states have authority within their states," Fleischer said at a September 23 news conference. "The President placed a series of ethical requirements" on stem cell research conducted with federal funds. "That's a federal matter. I don't comment on state matters. The President has put protections in place that he thinks are appropriate on the federal level."

He repeated the position in a press briefing the following day. "As President, that's not his purview," Fleischer said, "to sign or veto every bill passed by every legislature in every state.

"The President has spoken very plainly to the American people about the importance of creating a culture that values life. And in that, he differs with Governor Davis on this matter. The President has set forward a stringent set of federal guidelines to make certain that ethical considerations are put in place ... that values the culture of life. And that's what the President has done on the federal level."

Bush believes it is immoral to exploit embryos to create new stem cell lines because "even the most noble ends do not justify any means." The President's supporters on this issue, including anti-abortion groups and the Roman Catholic Church, contend embryonic stem cell research is murder, as it starts with the destruction of a human embryo.

In keeping with the "states' rights" theme, New Jersey State Senators Richard J. Codey and Barbara Buono introduced a measure (S 1909) similar to California's on September 30. Their counterparts in the State Assembly, Assemblymen Neil M. Cohen, John F. McKeon, and Mims Hackett Jr. followed with an identical measure (A 2840) on October 3.

According to Ortiz's office, New Mexico and Oregon may be considering similar bills. The National Conference of State Legislatures reports Maryland and Virginia are considering bills that would create special panels dedicated to exploring the potential of stem-cell research.

At the federal level, Senator Sam Brownback (R-Kansas) introduced in January 2002 a bill that would ban human cloning and impose criminal penalties on those found guilty of cloning or using embryonic stem cells or stem cell-derived therapies obtained through human cloning. The measure has 30 cosponsors and is identical to a House bill (HR 2505) passed in July 2001 by a 265-162 vote. If the Senate and House measures are combined and offered to the President, Bush has said he would sign it, which would make California's new law moot.

"[T]he Bush administration policy still trumps California law when it comes to federally funded researchers ... and the federal government provides roughly 90 percent of research funding in the U.S."

Diane Carol Bast is vice president of The Heartland Institute and editor of Health Care News. *Conrad F. Meier is managing editor of* Health Care News.

For more information…

WWW The full text of the California stem cell research law is available on the Internet. Point your Web browser to **http://www.leginfo.ca.gov/pub/bill/sen/sb_0251-0300/sb_253_bill_20020922_chaptered.html** for the HTML version, or **http://www.leginfo.ca.gov/pub/bill/sen/sb_0251-0300/sb_253_bill_20020922_chaptered.pdf** for the bill in Adobe Acrobat's PDF format.

The New Jersey measures are also available on the Internet. For the HTML version, go to **http://www.njleg.state.nj.us/2002/Bills/A3000/2840_I1.HTM**; for the PDF version, go to **http://www.njleg.state.nj.us/2002/Bills/A3000/2840_I1.PDF**.

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Merrill Matthews Jr., Ph.D., is a Heartland Senior Fellow specializing in health care policy and a visiting scholar with the Institute for Policy Innovation. Dr. Matthews is past president of the Health Economics Roundtable for the National Association for Business Economics, the largest trade association of business economists, and health policy advisor to the American Legislative Exchange Council, a bipartisan association of state legislators.

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AIDS continued from page 1

an academic researcher working on another survey, which is yet to be published and hence he wouldn't give full details, said the drop may only be 5 to 20 percent.

But whether it's 5 percent or 33 percent, any reduction at all seems inconceivable at a time when the developing world is finally waking up to the dangers of the AIDS pandemic; companies are giving drugs to Africa; and donations of more than $2 billion have already been sent to a new UN Global Fund on AIDS to purchase AIDS drugs.

Unintended Consequences

Dr. Des Martin, president of the South African HIV Clinicians Society, has his suspicions as to the cause. "Among several reasons, the threat of generic competition and attacks on multinational companies could be behind the recent decline in HIV anti-retroviral compounds," he noted.

The latter point is one the pharmaceutical industry apparently does not want discussed widely. According to Ruth Rabinowitz, a Member of Parliament with the South African Inkatha Freedom Party, "industry has been numbed into silence" by the activist and media attacks in South Africa and in the West. I could find no industry executives to go on the record.

One of the rare industry executives who would actually discuss the topic, but did not wish to be identified, agreed that although he didn't like to admit it, "we have lost the battle with the activists, and now the market is less profitable.

"While the government and activists blame capitalism, the drug giants, and profiteering, the latter actually develop solutions; the former just talk about them."

"The result is that we are spending less R&D time on anti-retrovirals. Why bother to innovate these products when any advance will not be profitable?" he said.

There may be one benign reason for having fewer products in development: When new approaches to combating a disease are tried, there may be numerous avenues of research begun, which subsequently are shown to be fruitless. Perhaps the drug development drop-off is because several research projects have been unsuccessful.

The anti-AIDS drugs that remain in development today are of higher quality and are more likely to succeed in clinical trials. The data could be slightly misleading, therefore, and the picture rosier than imagined.

But if that were the case, surely the industry would be spinning this line rather than ducking the question. It seems more likely that it's the lack of potential profitability that is driving industry away from research.

Patent Protection

After all, a reduction in research into AIDS would be consistent with drug companies' general message that patent protection is essential as an incentive for research. So perhaps governments should be strengthening patent protection on AIDS drugs.

Yet the UK government's recently formed Committee on Intellectual Property Rights (CIPR) calls for just the opposite approach in its first paper, "Integrating Intellectual Property Rights and Development Policy."

Although a scholarly work, the paper favors weakening patent protection of anti-AIDS drugs in developing countries. It hides this advice by using language of increasing generic competition for life-saving drugs and arguing that technology transfer will not occur quickly in countries with a Western-style patent system.

Although its technical arguments about access to drugs through parallel importing and compulsory licensing agreements may have some validity in strict economic theory, the disincentive to investment is massive. This report will send the wrong signals to an industry already moving away from AIDS drug development and into the more fruitful areas of erectile dysfunction, baldness, and hypertension.

Unintended Consequences

If the CIPR recommendations become policy, Africans may well have perfect access to drugs in a few years, only to find there are few drugs for the diseases they face.

In the past three years, activist groups like Doctors Without Borders have been celebrating the numerous climb-downs from the industry. Companies have been giving AIDS drugs away for free; they have drastically lowered their prices; and they have voluntarily licensed their drugs with generics manufacturers in South Africa. Meanwhile, in the boardrooms, decisions have been made to steer research in other directions.

It's ironic that activists have scared drug companies into action that will harm AIDS patients in the long run. While the government and activists blame capitalism, the drug giants, and profiteering, the latter actually develop solutions; the former just talk about them.

Roger Bate is a director of the South African NGO [non-governmental organization] Africa Fighting Malaria. This article was first published in the September 17, 2002 Web edition of the Jerusalem Post.

Bush Initiates Medicare Reform

Enlisting the private sector means seniors can get prescription drug coverage

BY CONRAD F. MEIER

Where Congress failed, the Bush administration has succeeded: It has found a way to initiate Medicare reform and offer prescription drug coverage to senior citizens. The three-year demonstration project doesn't require the approval of Congress.

"We'd like Congress to join us," said Health & Human Services Secretary Tommy Thompson when he announced the initiative, "but we will take the administrative actions we can while we are waiting for Congress to act."

President Bush meets with the Democratic members of Congress in the Oval Office to discuss his plan to improve Medicare. *White House photo/Paul Morse*

11 Million Eligible

Under the Bush initiative, senior citizens in 23 states will be given the opportunity to join new plans offered by 33 preferred provider organizations (PPOs) who have agreed to enroll Medicare beneficiaries. While roughly 11 million Medicare beneficiaries are eligible to participate, federal officials have no idea how many will choose to do so.

The Medicare PPO option will be available in Alabama, Arizona, California, Florida, Illinois, Indiana, Kansas, Kentucky, Louisiana, Maryland, Missouri, North Carolina, Nevada, New Jersey, New York, Ohio, Oregon, Pennsylvania, Rhode Island, Tennessee, Virginia, West Virginia, and Washington. Enrollment is expected to open in December, with coverage beginning in January 2003.

The PPO option offers more flexibility than either traditional fee-for-service Medicare or the troubled Medicare HMO program, Medicare+Choice. Participating PPOs agree to cover all services available under traditional Medicare and may choose to provide additional coverage, such as prescription drug benefits. Federal officials said all 33 PPOs intend to include some kind of prescription drug coverage in their Medicare plans.

The new PPO plans will allow Medicare beneficiaries to see doctors outside of plan networks, albeit for an increased co-pay or higher deductible. Under the more restrictive Medicare+Choice HMO model, beneficiaries typically must pay 100 percent of any charges incurred over-and-above the Medicare benefit in order to receive broader coverage, especially for prescription drugs.

Medicare has never before offered a PPO option, although PPOs are currently used by some 79 million Americans under age 65. Medicare should offer the same option, said Tom Scully, administrator of the Centers for Medicare and Medicaid Services (CMS), which runs the program. Scully has said he wants Medicare to function more like the private sector, last year telling the National Association of Health Underwriters that in the private sector, "the first concern is the beneficiary, not the bureaucracy."

Sharing the Risk

Responding to criticism from Families USA, which disapproves of the private sector's involvement in Medicare, Scully said, "The PPO plans will allow the government to test a new financing structure, in which the government and the private plans share financial risk instead of the plans bearing it alone."

Health and Human Services officials convinced the 33 PPOs to offer plans to Medicare beneficiaries by offering undisclosed "special financial incentives" and reducing their risk to claims losses. HHS will reimburse participating PPOs at either 99 percent of the rate for traditional fee-for-service Medicare coverage or 100 percent of the local Medicare+Choice rate, whichever is higher.

"[The Bush administration] has found a way to initiate Medicare reform and offer prescription drug coverage to senior citizens."

Medicare Reform?

The demonstration project is part of a broad Bush administration plan to tilt the government's vast health insurance system toward the private sector. The plan also reflects the determination of Bush's senior health advisors to begin refashioning Medicare, especially because several attempts by Congress this year to reform the program failed.

Conrad F. Meier is managing editor of Health Care News.

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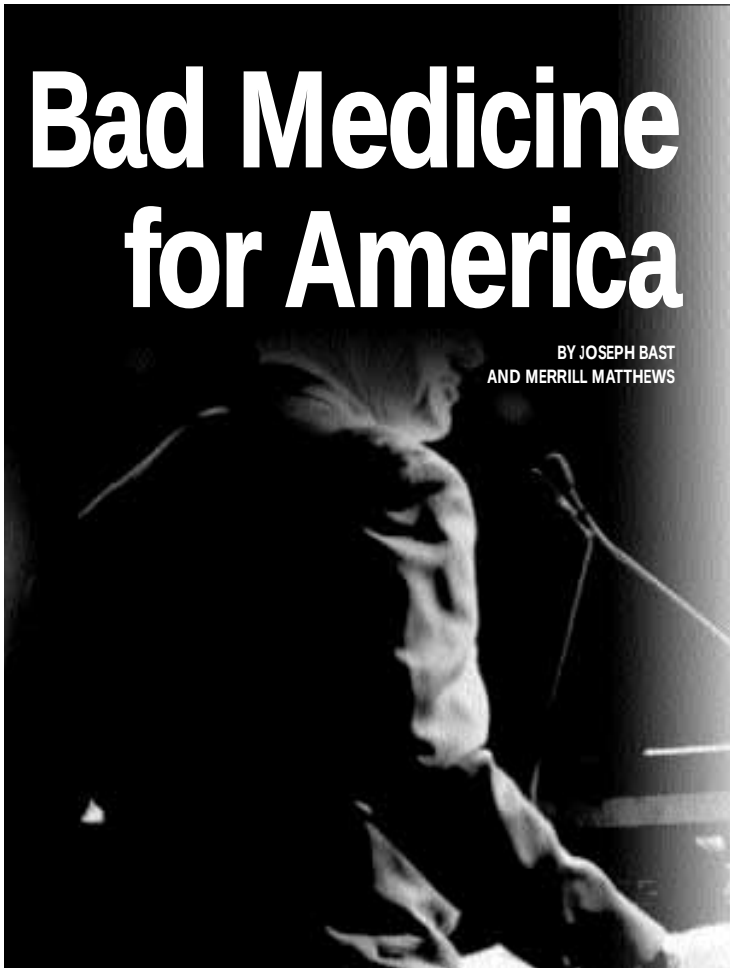
Bad Medicine for America

BY JOSEPH BAST
AND MERRILL MATTHEWS



Prescription drugs and their costs are high on political agendas this campaign season. Unfortunately, many candidates are seeking to score cheap points by attacking the nation's pharmaceutical industry, the most innovative in the world. We've heard the industry accused of free-riding off taxpayers, earning "huge profits" by manipulating patents, marketing "me too" drugs instead of finding new cures, and falsifying the results of safety tests.

The not-so-secret agenda of those making these misleading charges is to create a new prescription drug entitlement for seniors (and perhaps for everyone). By demonizing the drug industry, they hope to build public and political support for draconian price controls on prescription drugs.

"Price controls ... would cripple drug research and limit access to life-saving drugs, with terrible consequences for the health of all Americans."

Price controls have never worked, and they won't work this time on prescription drugs. Instead, they would cripple drug research and limit access to life-saving drugs, with terrible consequences for the health of all Americans.

Profits Before Patients?

A frequently made accusation is that the pharmaceutical industry puts "profits before patients." According to *Fortune* magazine's annual ranking of the top 500 companies, the 14 companies that make up the "pharmaceuticals" category had a median profit (as a percent of revenue) of 18 percent, more than any other industry's median.

The most profitable drug company on the *Fortune* list is Amgen (28 percent). Three other companies came in at 24 percent. Pharmacia and Abbott both report 7 percent, according to *Fortune*, and Gemzyne was at negative 9 percent.

But compare these numbers to Coca-Cola's 20 percent profit; Bank of New York (19 percent); Mellon Financial (33 percent—more than any drug company); Microsoft (29 percent); Oracle (24 percent); Gannett (publisher of *USA Today*—13 percent); Knight-Ridder (15 percent); AT&T (13 percent), and SBC Communications (16 percent).

The principal reason profits tend to be high in the pharmaceutical industry is because it is willing to take risks other industries avoid. Pharmaceutical companies invest about 17 percent of sales in research and development, more than nearly any other industry and well above the average for all industries of 3.9 percent.

Industry critics claim drug companies get a free ride from spending on basic research by the National Institutes of Health. But according to the Pharmaceutical Research and Manufacturers of America, the trade association for the manufacturers of innovative drugs, industry outspent NIH $26 billion to $18 billion in 2000. According to NIH itself, only four of the 47 best-selling drugs were developed in part with NIH funding.

New or "Me Too"?

According to PhRMA, 78 percent of the industry's spending on R&D goes toward finding new drugs. At the current time more than 400 new medicines for cancer, 122 for heart disease and stroke, and 24 for Alzheimer's are undergoing testing. The number of new drugs being produced is rising over time: Twenty new drugs were approved by the Food and Drug Administration in 1988 and 23 in 1989, compared with 27 in 2000 and 24 in 2001.

A recent study from a managed care advocacy organization claimed 80 percent of "new" drugs are not "significantly different" or "proven to be more effective" than drugs already on the market. Cost-cutters at HMOs might wish to tell their patients this, but it is impossible even for experts to characterize changes to prescription drugs as being medically "insignificant."

Doctors have different opinions about the best drugs and therapies available. That's not greed or conspiracy; it's medicine. No two patients are exactly alike, and no two doctors have past experiences so similar that they will always make the same diagnoses or prescribe the same medicines. In cases such as depression, where symptoms can change over time and are often elusive, the only way to determine the best drug for a patient is by trial and error.

Critics say changes that allow a drug to be taken less frequently are unimportant, but such a change is known to save lives. Getting patients, particularly those who are elderly, to take their medication on a prescribed schedule can be very difficult. Moving from two pills a day to one, or one a day to one a week, improves patient compliance and can prevent serious medical complications.

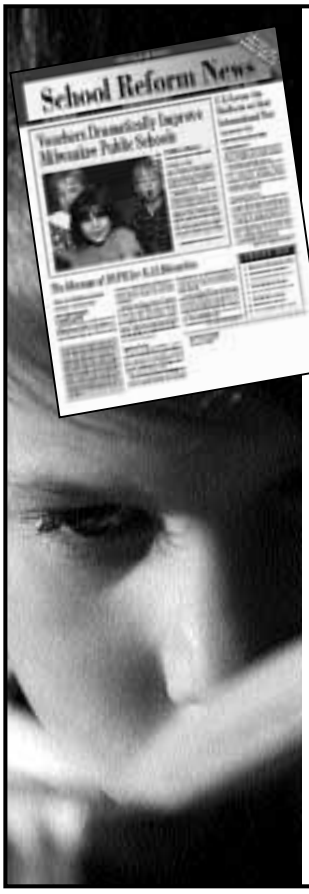
Critics allege that drug manufacturers are allowed to market new drugs that haven't been proven to be better than those already on the market. This is true. But why should a product have to be proven superior to all other products currently available before it can be sold? Such a requirement is not imposed on any other industry because competition among producers of very similar or even identical goods and services benefits consumers. It is by allowing producers to advertise the prices of competing products that markets ensure consumers get the best products at the lowest prices.

"[M]any candidates are seeking to score cheap points by attacking the nation's pharmaceutical industry, the most innovative in the world."

Exploiting Patent Protection?

Critics charge drug companies use patents to create monopolies on certain types of drugs so they can charge higher prices. However, there

MEDICINE continued on next page



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MEDICINE continued

are 170 drugs available for high blood pressure. Many of those drugs have existing patents. So what do we really have? Monopoly or strong competition?

The country's Founding Fathers thought intellectual property rights were so important that patents and copyrights are the only property rights affirmatively protected in the U.S. Constitution (Article 1, Section 8). Patents reward innovation by protecting an inventor from competition during the 20 years following the granting of a patent, provided the inventor makes public details about his or her invention.

The patent system has worked well in the drug industry. U.S. drug companies are responsible for some 90 percent of all the world's new drug discoveries each year, and a growing number of foreign drug companies are relocating to the United States to enjoy our patent protections.

This has not occurred at the expense of consumers. Generic drugs—inexpensive copies of innovative drugs—have rapidly increased their market share and now account for nearly 50 percent by volume of prescription drugs. That's clear evidence the nation's patent system is correctly balancing the interests of consumers and inventors.

Drug companies surrendered some of their patent protections a decade ago to allow generic manufacturers to begin selling products sooner than they otherwise could. This accommodation was made despite the fact that about nine of the 20 years of patent protection granted will be taken up with testing, trials, and FDA delays. This leaves the companies with only 11 years, on average, to recover their R&D expenses and earn a profit. And keep in mind that a patent doesn't mean no competition, only competition from marketers of exact duplicates of the patented medication.

"The principal reason profits tend to be high in the pharmaceutical industry is because it is willing to take risks other industries avoid."

Testing against Placebos

Some critics complain new drugs are tested against placebos rather than existing drugs. But the FDA set the rules this way, and drug companies have little control over the drug-approval process.

The FDA's drug-approval process requires new drugs to be safe and more effective than placebos, not more effective than existing drugs. Achieving this level of quality assurance requires nine years and costs more than $800 million to get a new drug approved in the United States. No one counts how many lives could be saved, or how much suffering would be avoided, if the approval process were shorter and less expensive.

Problems and side effects that might not show up in a sample of 3,000 people may show up when 100,000 or 1 million patients use the drug. When that happens, the drug companies may change the warnings on the labels or sometimes pull the drug off the market. No one can know all the possible side effects until a drug is distributed widely.

One of the more outrageous charges is that researchers cover up side effects and problems with new drugs because they make money off the research. However, research money from a drug company goes to the department of the medical school doing the research and does not enrich individual researchers. Moreover, researchers have to report back to the medical school's Institutional Review Board that oversees human research.

If anything looks suspicious, the IRB can request an explanation or stop the protocol. Sometimes the researchers stop it. But these trials typically involve 30 academic medical centers, 50 or 100 doctors, and perhaps hundreds of nurses and support staff. To imply that all of these scientists, administrators, doctors, and nurses are in the pockets of drug companies, and that their IRBs are all asleep at the wheel, is both insulting and ludicrous.

No Need to Demonize the Industry

Giving senior citizens greater access to prescription drugs is an important matter of public policy that ought to be widely discussed. But demonizing the prescription drug industry does not advance that discussion, and in fact turns our attention to false issues and policy proposals that simply wouldn't work.

Whether one drug is better than another is, and ought to be, decided by patients in consultation with their physicians. Only they can decide whether the trade-offs of benefits, costs, and risk are worthwhile. The political campaign will be full of people attempting to second-guess patients and their doctors. We should not go down that road.

Joseph Bast is president of The Heartland Institute, a public policy institute based in Chicago, and Merrill Matthews is an assistant editor for Health Care News. *This essay first appeared in the Sunday, September 22, 2002 issue of the* Chicago Sun-Times.

Maine Rx Price Controls Violate Medicaid Law

BY CONRAD F. MEIER

Maine's beleaguered prescription drug program is still under fire for violating Medicaid and interstate commerce laws. Although the bill was enacted by the state legislature in 2001, it has not yet taken effect.

The Pharmaceutical Research and Manufacturers of America (PhRMA) filed separate Supreme Court briefs in September 2001 objecting to Maine Rx, the price-controlled prescription drug program meant to address the rising cost of prescription medications.

Under the program, Maine officials would negotiate with drug makers for additional discounts similar to those given to the Medicaid program. Maine was to use the savings to reimburse pharmacies for giving discounts to customers who lack drug coverage. State officials estimate eligible residents would save between 10 and 30 percent on prescription drug costs under the program.

"PhRMA contends Maine Rx violates Medicaid law by making it more difficult for beneficiaries to obtain certain medications."

In an effort to encourage drug company participation, the program includes a provision under which doctors would be required to receive prior approval from a patient's health plan administrator to prescribe medications from companies that are not part of the program.

In 2000, PhRMA filed its first lawsuit against Maine Rx, arguing the state was not authorized by federal Medicaid law to adopt such a program, and that the program represented a "burden on interstate commerce."

Initially, a federal district court in Maine ruled in favor of PhRMA, but in May 2001 the 1st U.S. Circuit Court of Appeals in Boston overturned the decision and said the program could go forward. Also in May, the Bush administration asked the Supreme Court to reject the PhRMA appeal, but in June the Court agreed to hear the case.

Illegal Program?

In its most recent brief, PhRMA contends Maine Rx violates Medicaid law by making it more difficult for beneficiaries to obtain certain medications. "In effect, Maine is holding Medicaid patients' prescription drug benefits hostage to the state's fundraising efforts on behalf of others outside the Medicaid program," the brief states.

PhRMA also argues the program violates the Constitution's interstate commerce provisions, which prohibit a state from regulating businesses outside its borders. Under Maine Rx, rebates would be extracted from out-of-state drug companies not conducting business directly with the state, but rather dealing with wholesalers within the state, the brief explains.

In its own brief in the matter filed last September, the Department of Justice (DOJ) agrees Maine Rx is illegal, but for a "much more limited reason" than PhRMA asserts. The DOJ said the program is illegal because it is not "specifically targeted to people who are poor or elderly, or who have a different need for help in paying for medicine."

The White House noted that despite its objections to Maine's program, it wants to encourage states to continue experimenting with ways to lower prescription drug prices.

"Nobody should say we are supporting PhRMA over Maine," an anonymous administration spokesperson said, adding that Health and Human Services in October 2001 encouraged states to submit proposals for increasing access to prescription drugs for low-income residents who do not qualify for Medicaid.

The Rx Football

Newsday reports that in Maine's U.S. Senate race, the issue of prescription drug coverage has played a key role, with Democratic candidate and former State Senate Majority Leader Chellie Pingree making prescription drugs the centerpiece of her campaign platform. Pingree helped write the legislation authorizing Maine Rx and has traveled around the country explaining why similar programs should be implemented nationally.

But incumbent Senator Susan Collins (R-Maine) is working to neutralize the traditional Democratic advantage on health care issues. Collins was placed squarely in the middle of the nation's health care debate earlier this year as one of the sponsors of Senate-passed legislation (SB 812) that aimed to increase access to generic drugs by using price controls. While the Senate bill failed in the House of Representatives, it remains a meaty issue in the political football game.

The Maine election also has drawn the interest of AARP, the national senior advocacy group, which is spotlighting the race and coordinating events designed to keep citizens focused on the prescription drug benefit.

Conrad F. Meier is managing editor of Health Care News.

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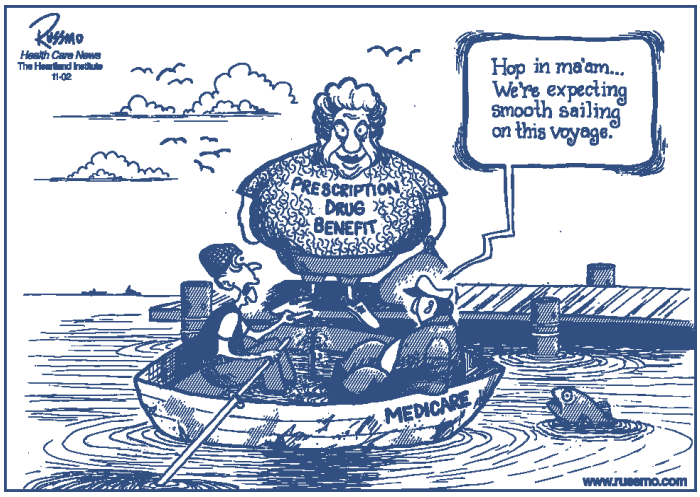
Should the Medicare Bureaucracy Manage a Drug Benefit?



BY ROBERT E. MOFFIT, PH.D.

Many Members of Congress want the current Medicare bureaucracy to manage a new Medicare prescription drug benefit.

But a major government-wide survey of federal managers, conducted by the U.S. General Accounting Office (GAO), found the Centers for Medicare and Medicaid Services (CMS)—the federal agency that runs the Medicare program—is one of the most poorly performing agencies of the federal government.

In May 2001, the GAO, the fiscal watchdog agency of Congress, released *Managing for Results: Federal Managers' Views on Key Management Issues Vary Widely Across Agencies*, a survey of federal managers in 28 federal agencies.

GAO investigators were trying to determine the degree to which federal agencies were meeting their management objectives under current law. The GAO found the CMS ranks at or near the bottom in many managerial categories.

For example, the CMS ranked

- at or near the bottom in key measures of managerial performance.
- dead last in terms of the percentage of managers who reported having key performance measures for their work.
- near the bottom in measures of customer service.
- next to last in having a measure for customer service as part of its managerial culture.
- near the bottom in measures of accountability for results.
- next to last among federal agencies in having a management team that was held accountable by performance measures.

Of CMS managers surveyed by the GAO, 16 percent reported having customer service measures to a "great extent" or to "a very great extent." Only the Nuclear Regulatory Commission, with just 14 percent of managers reporting the presence of such measures, scored lower in this category.

Need a Better Program

For years, Medicare trustees and responsible officials at the GAO and Congressional Budget Office (CBO) have warned Congress it would be a profound mistake simply to add a Medicare prescription drug benefit to the current Medicare program without serious structural reform.

Not only would such an additional responsibility aggravate the growing financial pressures on the program, but it would also complicate what has already become a serious and largely neglected Medicare managerial problem.

"[A] major government-wide survey of federal managers, conducted by the U.S. General Accounting Office (GAO), found the Centers for Medicare and Medicaid Services (CMS) ... is one of the most poorly performing agencies of the federal government."

In a recent National Academy of Social Insurance (NASI) report, a philosophically diverse panel made several recommendations on how to improve the governance of the Medicare program.

The report declared: "In the absence of a decision by Congress to fundamentally reform Medicare, or provide substantial new investment of resources, both financial and human, the study panel urges Congress not to enact major changes in the program in the near term because CMS does not currently have either the resources or the capacity to implement such changes in a timely fashion."

Best Solution

The best solution is to transform Medicare into a program that more closely resembles the popular and successful Federal Employees Health Benefits Program (FEHBP) that covers members of Congress, federal workers, and retirees.

These enrollees not only have access to solid prescription drug coverage, but can also choose better health plans if they wish to do so. Not surprisingly, the GAO ranked the Office of Personnel Management (OPM), the agency that administers the FEHBP, the highest among federal agencies in terms of the percentage of federal managers who reported they had the authority to get results.

The OPM also ranked first among agencies in its use of performance information in managing its responsibilities.

Intermediate Steps to Reform

If Congress is reluctant to re-create the fundamental structure of Medicare on the FEHBP model in a single legislative act, it could at least start the transformation to a new and better system. It could do this by allowing new retirees to keep their private health plan and drug coverage and to take it with them into retirement as their primary coverage should they wish to do so.

To offset the cost of this, Congress would provide a government contribution in the form of premium support. Congress could thus phase in Medicare reform gradually, enabling the first wave of retirees from the huge baby boom generation to take advantage of a flexible new program with richer and more varied benefits.

Meanwhile, Congress would have an opportunity to make any necessary adjustments to the program over time. Congress could also help the CMS function more effectively by streamlining CMS responsibilities and allowing CMS staff to concentrate time, effort, and resources on the traditional Medicare fee-for-service program, rather than trying to run the "Medicare+Choice" system of private health plans or implementing a complex new drug benefit.

Robert E. Moffit, Ph.D. is director of domestic policy studies at The Heritage Foundation. This article is an abbreviated version of his September 9, 2002 Executive Summary #1583, *available at* http://www.heritage.org *under the title, "Congress Should Think Twice About Allowing the Medicare Bureaucracy To Manage a Drug Benefit."*

EXECUTIVE SUMMARY

Prescription Drug Security Plan (PDS)

The Galen Institute

For more information…

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The program has two parts:

1. An up-front subsidy for routine drug expenses
2. Coverage for high-end and catastrophic drug costs

The PDS plan provides a generous up-front subsidy of $600 a year to help low- to moderate-income Medicare beneficiaries with their routine drug purchases. Those at 200 percent of poverty and below would receive the full $600, deposited to their personal PDS card account. In addition, they would receive fully subsidized private insurance coverage for larger drug expenses.

The private catastrophic coverage would pay 80 percent of beneficiaries' drug costs between $2,000 and $6,000 a year, with full coverage above $6,000. Deposits to the PDS card and premium subsidies are gradually reduced for those between 200 percent and 350 percent of poverty. Medicare beneficiaries with higher incomes would get a tax deduction for making their own card deposits and paying their catastrophic insurance premiums. Everyone is eligible for competitively negotiated drug discounts.

Structure of the Benefit

Medicare beneficiaries would receive prescription drug coverage for both routine drug purchases and catastrophic expenses, organized through private, competing plans.

The coverage would include a PDS card with subsidies of up to $600 a year for the purchase of routine medicines. Any unspent balances could be rolled over to the next year to encourage seniors to make wise purchasing decisions.

Catastrophic coverage is provided in two parts: Beneficiaries pay 20 percent and the plan pays 80 percent for drug spending from $2,000 to $6,000 a year. Full coverage triggers at $6,000.

Subsidies to the card account and premium subsidies are gradually reduced as beneficiaries' incomes increase, ending at 350 percent of poverty. Those with incomes above the subsidy thresholds could participate in the program by creating their own PDS card account and receiving a tax deduction for their $600 contribution and for the cost of their catastrophic insurance premium.

All participants in this voluntary program would be eligible for discounts negotiated by their plans and could select plans that offer them the best prices on the drugs they need,

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Medicare Drug Follies

BY MICHAEL GLUECK, M.D.
AND ROBERT J. CIHAK, M.D.

Our senior citizens should have the life-saving medicines they need without going broke or giving up life's other necessities in the process. However, we need to inject or infuse a dose of common sense into the treatment plan.

We won't anesthetize you with a scorecard on the current congressional "bidding wars" (as Grace-Marie Turner of the Galen Institute calls them) regarding Medicare drug coverage. Suffice it to note our legislators get re-elected by bringing home the tofu. Suffice it also to note Medicare is a political animal, and subject therefore to all the vagaries and ills of that sadly un-endangered species.

And so it will be if and when the government assumes a virtual monopoly on providing prescription drugs to Medicare patients.

Biting the Hand

Members of Congress apparently believe, as did the HMOs in the beginning, that they can bring down costs by "negotiating" with the drug companies. Yes, there can be short-term savings by squeezing out "inefficiencies." But after the squeeze, what happens? Rising costs force cutbacks in drug development, which is a notoriously risky and inefficient undertaking.

As Turner points out, "Between 1975 and 1994, the United States developed 45 percent of new major drugs, while France produced 3 percent, Germany 7 percent, and Britain 14 percent." The European problem wasn't lack of pharmaceutical smarts—it was lack of funds, and the unlikelihood (caused by weak patent protections) of a reasonable return on investment.

So far, the United States has been relatively lucky with Medicare, given that even its original backers—a combination of welfare-state zealots and venal pols—knew the system wasn't sustainable.

Unfortunately, it took several decades for the predictable problems to meld into the Insanity that Dares Not Speak its Name. In a rational, i.e., market, economy, when people want more of something, they get it, often at reduced cost. In government-run medicine, the more people want, the less they get, and at increased cost to all.

Members of Congress know that nearly all legislation ends up in court, where the judges decide what they think they meant. Congress also knows bureaucrats will write, usually in secret, detailed "interpretative" regulations. But Congress also loves its loopholes and set-asides and special constituents and exceptions, so vague verbiage now co-exists with hundreds of pages of micro-management and dishonesty.

Turning Issues into Laws

Which brings us to another normal-seeming, yet foolish pattern : how social engineers turn issues into laws. The tactic has worked since the Progressive Era.

First, find some problem, real or imaginary. Next, redefine the problem as a "crisis"—an imminent calamity only the government can solve. Next, redefine the proposed "solution" as a "right" or an "entitlement." Then pass legislation that not only won't work, it can't possibly work ... and it will in fact create more problems, which can in turn be redefined as new crises.

Federal control of drugs must inevitably lead to rationing. When something is perceived as "free," especially something as vital to seniors as medical care, demand soars beyond any government's ability to provide. So we all end up with the worst of both worlds: fewer new drugs, straightjacketed access to current drugs, and yet another crisis requiring yet another government solution.

The mess is totally unnecessary. Most senior citizens in the U.S. already have drug insurance. Others, who may not have such insurance because they don't need it, use their own resources to pay for their prescriptions. And there's no shortage of workable proposals for getting insurance to those who need it.

For one example, consider the Prescription Drug Security Card Plan, summarized below, developed by the Galen Institute and American Enterprise Institute. The plan would provide a subsidy directly to needy seniors "to purchase needed medicines and also to provide them with insurance protection against the risk of high prescription drug costs."

When Failure Is a Success

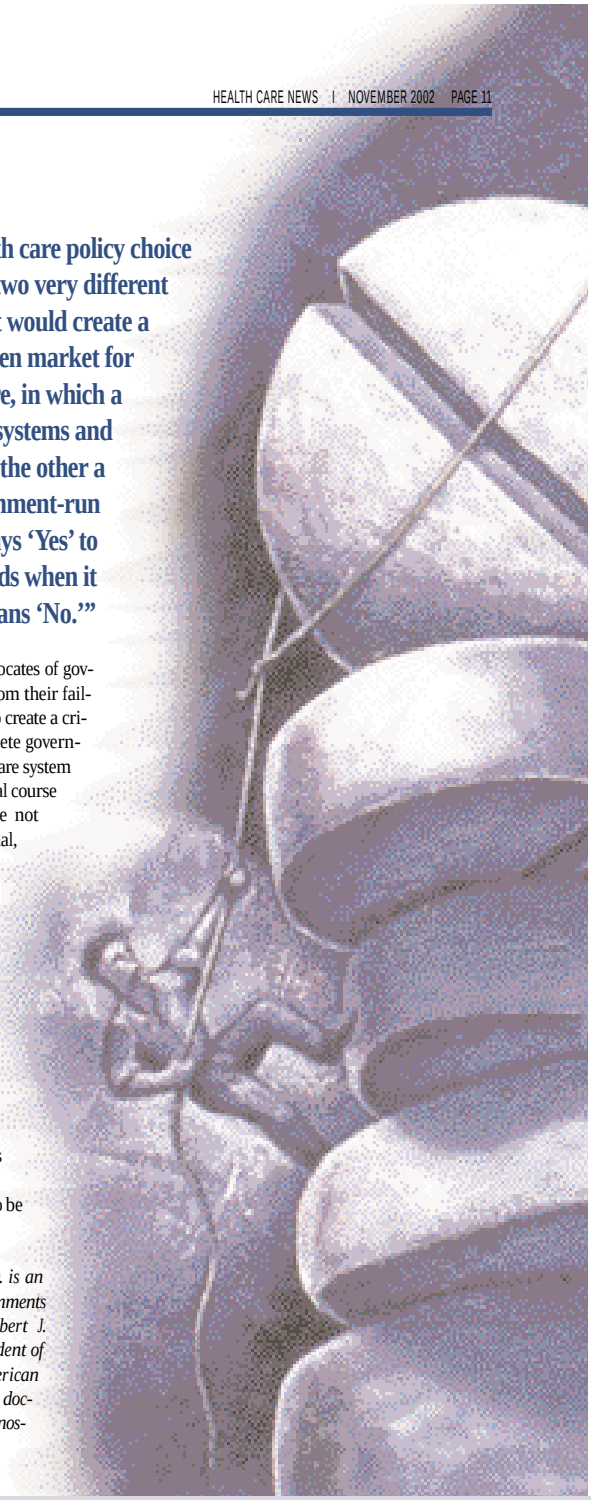
But perhaps the greatest madness lies in our failure to recognize that the advocates of government medicine *benefit* from their failures. Their goal, after all, is to create a crisis situation in which complete government takeover of the health care system appears to be the only rational course of action left. Perhaps we're not many years away from that final, graceless surrender.

> **"Today, the health care policy choice may be between two very different visions: one that would create a genuinely open market for medical care, in which a variety of systems and plans compete; the other a monopoly government-run system that says 'Yes' to all your needs when it really means 'No.'"**

Today, the health care policy choice may be between two very different visions: one that would create a genuinely open market for medical care, in which a variety of systems and plans compete; the other a monopoly government-run system that says "Yes" to all your needs when it really means "No."

The choice would appear to be ours.

Michael Arnold Glueck, M.D. is an award-winning writer who comments on medical-legal issues. Robert J. Cihak, M.D. is a former president of the Association of American Physicians and Surgeons. Both doctors are Harvard-trained diagnostic radiologists.



without the limits on choices that would be likely in government-run plans.

Advantages of the PDS Plan

- The biggest subsidies are targeted to low- and moderate-income seniors.
- The program minimizes adverse selection in the catastrophic plan by encouraging healthy beneficiaries as well as those who are sicker to participate in order to get the PDS card deposit, catastrophic coverage, and drug discounts.
- The PDS plan would set in place an infrastructure for overall Medicare reform by establishing an office much like the Office of Personnel Management that oversees the Federal Employees Health Benefits Program. This office would, among other things, qualify the competing private drug plans and provide information to seniors about choices.
- Drug discounts would be privately negotiated, and the government would not set price controls or decide which drugs would or would not be available to plan participants.
- Participation in the program is voluntary and open to all Medicare beneficiaries.
- Because the plan targets the greatest assistance to lower-income seniors, it would be less likely to crowd-out the existing private coverage that millions of seniors already have.

Cost to the Federal Government

PricewaterhouseCoopers estimates the PDS plan would cost $302 billion over 10 years.

SUBSIDY LEVELS

Beneficiary poverty level	Annual PDS card deposit	Federal premium subsidy	Beneficiary's monthly premium
Under 200%	$600	100%	$0
200-250%	$450	75%	$28
250-300%	$300	75%	$28
300-350%	$150	Phases out	$28 - $111
Above 350%	Tax deductible to $600	Fully tax-deductible	$111

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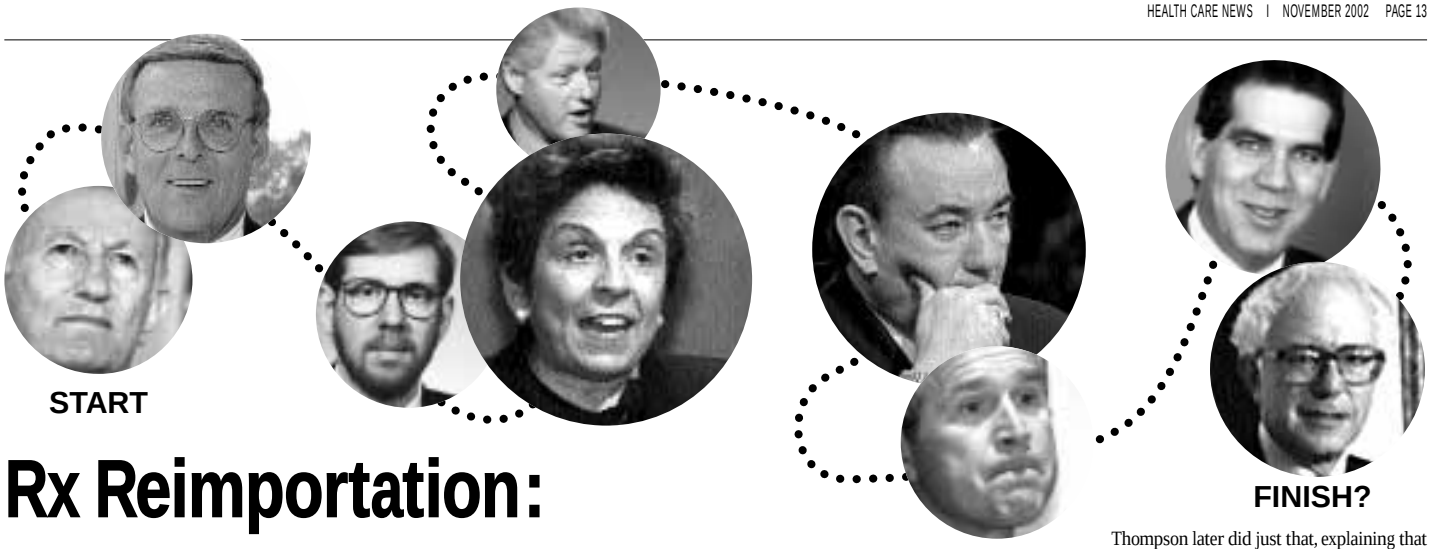

Rx Reimportation: *A Legislative History*

BY DEMETRIOS L. KOUZOUKAS

In the absence of any Congressional action on a Medicare prescription drug benefit, some states have focused instead on immediate, incremental measures such as drug discount cards and drug reimportation. The history of drug reimportation should be of interest to its current advocates and critics alike.

Importing Our Exports

Drug reimportation refers to allowing prescription drugs produced for use in another country to be imported into the U.S. for sale here instead. Because these drugs were often originally manufactured in the U.S., and then exported abroad, their return to the U.S. has been termed "reimportation."

Under current law, only pharmaceutical manufacturers themselves are allowed to reimport prescription drugs, and even then only under the Prescription Drug Marketing Act of 1988. They do—to the tune of $13 billion per year.

However, an amendment to the FY 2001 agricultural appropriations bill passed in October 2000, called the Medicine Equity and Drug Safety Act, opened up the possibility of drug reimportation by private importers.

That language required manufacturers or importers to certify to the Food and Drug Administration (FDA) that they tested reimported drugs for authenticity and degradation and to confidentially submit the test results to the FDA. The law also directed the FDA and General Accounting Office to conduct studies addressing compliance with testing requirements, effect on trade and patent rights, and effect on retail prices.

Finally, the law limited the potential source of reimported drugs—mainly the EU countries, Australia, Canada, Israel, Japan, New Zealand, Switzerland, and South Africa. It also provided $23 million in funding for FDA oversight of reimportation, such as the required batch testing to ensure authenticity and purity—a level of funding that was supposed to get the FDA started on a reimportation oversight program, and supposed to become available "only upon submission of an official budget request and justification of such amount by the president to the Congress."

The legislation was largely pushed through by the efforts of Senators Byron Dorgan (D-North Dakota) and James Jeffords (I-Vermont, then Republican), who cited the support of former FDA Commissioner David Kessler and Secretary of the Department of Health and Human Services (HHS) Donna Shalala.

Clinton: "Empty Promise"

FDA officials and the drug industry contemporaneously expressed strong concerns that reimportation could facilitate entry of impure, counterfeit, or less efficacious drugs into the United States.

"Drug reimportation refers to allowing prescription drugs produced for use in another country to be imported into the U.S. for sale here instead."

Critics of drug reimportation also argued implementation of the law would cause manufacturers and wholesalers to curtail supplies in some markets and redirect them to others offering better margins.

One example is the recent redirection by wholesalers of supplies of Bayer's anti-anginal drug Adalat (nifedipine) intended for use in Spain and France to the United Kingdom, where the price is higher.

Although President Bill Clinton signed the Medicine Equity and Drug Safety Act into law on October 28, 2000 as part of an omnibus appropriations bill, he attached it as an "empty promise" and criticized the law because, he said, it contained "several loopholes that effectively render [it] meaningless."

Specifically, Clinton cited the five-year sunset provision as discouraging investment and the ability of drug manufacturers to deny drug reimporters access to required FDA-approved labeling.

Then, Shalala repeated Clinton's criticism when, on December 26, 2000, she refused to make the required determination that the law 1) posed no additional risk to public health and safety and 2) significantly lowered the cost of prescription drugs. Under its own terms, the drug reimportation provision could not go into effect without that determination. The *Washington Post*, *New York Times*, and *Los Angeles Times* praised Shalala's decision.

The issue was revived, however, when Jeffords, a central proponent of drug reimportation and then Chairman of the Senate Health, Education, Labor and Pensions Committee, released a Congressional Research Service legal analysis that found Shalala's decision "does not preclude" future HHS secretaries from making the prerequisite determination.

Bush: "Looking Doubtful"

Incoming HHS Secretary Tommy Thompson, in his confirmation hearing before Jeffords' committee, promised he would "revisit Shalala's determination." During the campaign, President George W. Bush had said the reimportation plan "makes sense" as a way to provide "an immediate helping hand" to the elderly.

Accordingly, Jeffords and a bipartisan group of 15 other Senators and members of the House of Representatives repeatedly wrote Bush to ask Thompson to reverse Shalala's decision. Nonetheless, the Bush administration remained non-committal in early 2001. When asked about drug reimportation, Press Secretary Ari Fleischer simply said, "Let me take that question and get back," and "I don't have anything for you on that." Thompson was similarly cagey in his confirmation hearing and appearances in budget hearings.

Just in case, however, Representative Peter Deutsch (D-Florida) reintroduced in the 107th Congress a drug reimportation bill, H.R. 58, addressing the issues identified by Shalala. Another reimportation bill, H.R.698, is sponsored by Rep. Bernie Sanders (I-Vermont) and the Congressional Progressive Caucus.

When Bush's new budget blueprint came out, it included an omen for the drug reimportation program—a $20 million cut from the $23 million set aside to implement it. The 90 percent budget cut, along with Thompson's statement that such reinstatement is "looking doubtful," signaled he would eventually follow Shalala's lead in refusing to implement the program.

Thompson later did just that, explaining that the required certification "is a pretty difficult test. I can understand why [former Secretary] Shalala said it is difficult." Thompson went on to say that "at first cut," it is "impossible" to do such a certification and that "we would have to increase the number of inspectors by quite a large degree in order for us to certify that they're the same drugs and that they're going to be safe for the consuming public in America."

In response, reimportation supporters, somewhat emboldened by the turnover in control of the Senate, from Republican to Democrat, resulting from Jeffords' switch in party affiliation, succeeded in passing reimportation legislation in this Congress.

Reimportation efforts continue at the state level as well. Eastern Maine Healthcare, a five-hospital network in Maine, says it will operate an international mail-order pharmacy in Canada. The pharmacy will sell 90-day supplies of drugs to U.S. citizens through the mail, but at Canadian prices—so long as customers' doctors have special "border licenses" to prescribe drugs in New Brunswick.

"FDA officials and the drug industry ... expressed strong concerns that reimportation could facilitate entry of impure, counterfeit, or less efficacious drugs into the United States."

Reimportation attempts to borrow the benefits of price controls and other pharmaceutical industry regulations in other countries without bearing the concomitant economic costs in terms of potential loss of quality, consumer safety, and unintended changes in pharmaceutical companies' sales and marketing practices. It seems certain such efforts will continue.

The main question surrounding reimportation will continue to be what extent reimportation also brings in these other costs along with lower prices.

Demetrios L. Kouzoukas is a lawyer at Gardner, Carton & Douglas who specializes in health law. He is a frequent contributor to Health Care News. *The views expressed and implied herein are solely those of the author, and they are not to be attributed to Gardner, Carton & Douglas, nor copied or distributed without this disclaimer.*

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IRS Ruling Expected to Increase HRA Participation

BY PETER NEURATH

A June 2002 ruling by the Internal Revenue Service may boost sales of defined-contribution plans by health insurance companies, but it's debatable whether the decision will slow spending on health services.

The ruling pertains to so-called "health reimbursement arrangements," HRAs, through which employers contribute funds to employees to pay for health services or reimburse employees for medical expenses.

Up to now, employers have been reluctant to use HRAs because the IRS had taken no position as to whether employers may fund HRAs with pretax dollars, and had not given employers guidance on their use. "There was a cloud of uncertainty," said Issaquah health policy expert Dr. Steve Barchet, former deputy surgeon general for the Navy.

"Cloud of Uncertainty" Gone

In a June 26, 2002 ruling, the IRS removed that cloud.

It's now clear that employers may fund HRAs with money that's not taxable; that employees may use the money to buy health insurance and medical services; that employees may carry over unspent HRA funds, free of taxes, to the following year; and that employees retain access to HRA funds when they change jobs or retire.

"This is a significant change," said consultant Larry Chapman, chairman of Summex Corp. "We're likely to see a very rapid expansion" of employer-sponsored health plans using HRAs.

Employers now can safely use HRAs in defined-contribution health plans, which are still relatively new to the market but are attracting interest in the business community as a way to control rapidly rising health care costs.

Defined-Contribution Plans

In a written summary and discussion of consumer-driven health plans, Barchet and Chapman identified the characteristics of defined-contribution plans, including the following:

- Employers make fixed-dollar contributions to employees to pay for health insurance.
- Employees are given choices among health plans that vary in deductibles, copayments, premium levels, and types (such as HMOs and preferred provider organizations).
- Employees pay the difference between employer contributions and the premium charged by the health plans they choose.

In Washington, two health insurance companies now market defined-contribution plans. Last year, in partnership with Portland-based MyHealthBank, Regence BlueShield introduced a product enabling employers to make defined contributions that employees use to pay for the Regence health plan of their choice.

"'We're likely to see a very rapid expansion' of employer-sponsored health plans using HRAs."

Funds not spent on health insurance are placed in pretax, accruable accounts that employees may use to pay for deductibles, co-pays, eyeglasses, and orthodontics.

Regence officials said it's too early to speculate on whether the IRS ruling on HRAs will boost sales of their product.

Last year, Aetna began marketing to large employers a consumer-directed plan, of which defined-contribution plans are a subset. In July 2002, the carrier followed up with a plan for mid-size employers.

The product combines insurance for serious illnesses and high-cost medical expenses with a

IRS continued on next page

IRS Ruling Makes Patient Choice A Reality

BY PETE DU PONT

There is a saying I often think of when discussing the Internal Revenue Service (IRS): "Bureaucracy is the art of making the possible, impossible." But every now and then even the IRS surprises me by doing the exact opposite.

This summer the IRS released guidance on the use of "Health Reimbursement Arrangements" (HRAs) by employers. This action adds another important tool to the effort to restore patient power to a health care financing system that has become ever more dysfunctional over the years.

Irony, but Justice as Well

It may seem ironic that a bureaucracy like the IRS should move so decisively while the United States Congress has spent the better part of a decade on issues like the Patient Bill of Rights and prescription drugs in Medicare, without resolution. There is irony, but also justice in the action. After all, it was the IRS that set us on the path to the current employer-based system more than 50 years ago, when it decided the value of employer-sponsored health insurance benefits would not be considered "taxable income" to workers.

That simple decision gave employer-financed health insurance an enormous advantage over all other means of paying for health services. Benefits sponsored by an employer are free of all taxes, state and federal, income and payroll, while health insurance purchased by an individual, or health services paid for directly by a patient, enjoy no tax advantage at all.

The HRA ruling continues to rely on employers as the source of health care financing. But it does not require that financing be in the form of a health insurance program. Rather, it allows employers to make funds available so that employees can pay directly for services, and benefit from any cost savings they achieve. It gives employees wide latitude to choose the services and providers they prefer, without being confined to a specific benefit design. It gives workers a source of funds that may be used to continue their coverage after they leave a job, or help with their medical costs once they have retired.

"This action adds another important tool to the effort to restore patient power to a health care financing system that has become ever more dysfunctional over the years."

Importantly, the IRS has allowed an enormous amount of flexibility in program design—far more than is allowed under other efforts, such as Medical Savings Accounts (MSAs) or Flexible Spending Accounts (FSAs), which were micromanaged by Congress to a degree that limited their availability and attractiveness. Because of this flexibility, it is difficult to imagine an employer who would not want to offer an HRA in the next few years.

An HRA Primer

So what exactly is an HRA? An HRA is an amount of money allocated by an employer to the benefit of an individual employee. The HRA must be funded solely by the employer, and the funds may be used only for medical expenses. The account may never be "cashed out" to be used for non-medical expenses, but any amount not used within a year may be rolled-over into the following year and continue to be available to pay for health care services.

As long as those provisions are met, the money is not considered income and is as free of taxes as the rest of the employer's benefit plan. Importantly, the employer may continue to make the funds available even after a worker has retired or moved on to another job. Thus, the HRA amounts to a rainy day fund that could be used to pay COBRA continuation premiums while a worker is unemployed, or Medigap premiums when he or she is retired and eligible for Medicare.

Amazingly, beyond those broad principles, the IRS has left the program design up to the employer. There are no requirements for the underlying insurance program. One employer might have an insurance plan with a $4,000 deductible and put $3,000 into each worker's HRA. Another might have an HMO with a $25 co-pay for doctor visits, and put $100 a year into the HRA.

Yet another might have a mix—co-pays for prescription drugs, a deductible for hospital care, first-dollar coverage for preventive care, and a 20 percent co-insurance for physician visits—paired with an HRA to help cover all of those out-of-pocket expenses. Some employers might even offer no insurance plan at all, but put the entire contribution into an HRA so workers can choose their own plan.

Now if Congress could be half as responsive as the IRS has been, we might be able to open up MSAs and FSAs to wider segments of the market. They should give all three approaches a chance to find their own market niche and bring patient empowerment to all segments of America.

Pete du Pont is policy director for the National Center for Policy Analysis (NCPA) and a regular columnist on www.opinionjournal.com, *the editorial page Web site of* The Wall Street Journal. *du Pont's "Outside the Box" column appears online every Wednesday and discusses current public policy and political matters.*

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IRS continued

"health fund." Into these health funds employers contribute $250 for individual employees and $1,000 for families. Employees control how these funds are spent on covered services.

Spending Control Mechanism?

In a July editorial, the *Wall Street Journal* waxed enthusiastic about the IRS ruling and said HRAs will help control health care spending. Barchet and others, however, question whether that will occur.

Barchet said that unlike medical savings accounts, HRA funds are owned by the employer, not by employees. Employers make the funds available to employees to pay for health insurance and medical services. And that may affect how much employees spend on health care.

"[E]mployers may fund HRAs with money that's not taxable; ... employees may use the money to buy health insurance and medical services; ... employees may carry over unspent HRA funds, free of taxes, to the following year; and ... employees retain access to HRA funds when they change jobs or retire."

By contrast, Barchet said, money in medical savings accounts belongs to the employees, who can withdraw the money for other uses provided they pay taxes on the withdrawals.

Medical savings accounts were authorized by the 1996 Health Insurance Portability and Accountability Act. But the number of MSA plans is capped at 750,000 nationally, and the act makes the plans available only to firms with fewer than 50 employees.

The cost-controlling effect of medical savings accounts is that employees know they're spending their own money, according to Pat Rooney, former chairman of Golden Rule Insurance Co., a Lawrenceville, Illinois carrier that markets MSAs. The money goes with them when they leave. Employees can use it for an extra pension benefit at retirement or can take it out as a rainy day fund by paying excise tax on early withdrawal.

Rooney predicts HRAs, by contrast, will neither increase employee satisfaction nor control costs.

"When insured persons have a fund that will pay their deductible for them," he said, "they not only spend the money in the fund, but their consumption goes into the umbrella insurance that follows after the deductible, and the cost of the umbrella insurance is increased by at least a third."

Peter Neurath writes for the Puget Sound Business Journal, *a newspaper belonging to American City Business Journal Inc. This article is reprinted from that publication with permission. Contact the author at* pneurath@bizjournals.com.

BRITAIN continued from page 1

star hospital trusts to become independent, non-profit organisations or foundation hospitals. According to government insiders, this idea is certain to be implemented and all that remains is to tie up the legal and administrative detail. In Mr. Milburn's vision, some primary care trusts may also be given "foundation" status.

How could these ideas be put into practice? Once the Blair reforms are implemented, there will be 28 strategic health authorities in England supervising a larger number of primary care trusts (PCTs). The trusts are to be the main buyers of services from hospitals, which will be subject to a regime of inspections and monitoring by central government. How could this system be made more responsive to consumers?

Consumer-Driven

One possibility would be to convert PCTs to mutual organisations owned by their members. At a minimum this would require direct representation of patients on the controlling body of the PCT, but it would be better to go a step further to create real ownership by giving members personal control of the financial allocation PCTs receive from the Treasury for each patient. Better still, members should be allowed to take this amount with them to another PCT to give trusts an incentive to improve.

Mr. Milburn has said he wants the NHS to be "consumer-led," and such a change would go some way towards empowering patients. But PCTs would still have cash-limited budgets set by central government. To overcome this problem, people need to be free to add to the funding available to their PCT, but how can such freedom be made compatible with social solidarity?

One method would be to let PCTs establish separate mutual funds for service development. Members could pay into the fund just as they pay into any savings account. Interest would be free of tax and payable so long as the capital were tied up for long enough to allow its use for investment in health facilities, perhaps until retirement age.

Once the members reached the age of 65 the capital could be withdrawn or left to gather further interest. Each year huge amounts are invested in pensions and, if the tax regime for mutual health funds were the same as it is for pensions, it is possible many people would be willing to invest in mutual health funds as a way of combining provision for retirement with support for the NHS.

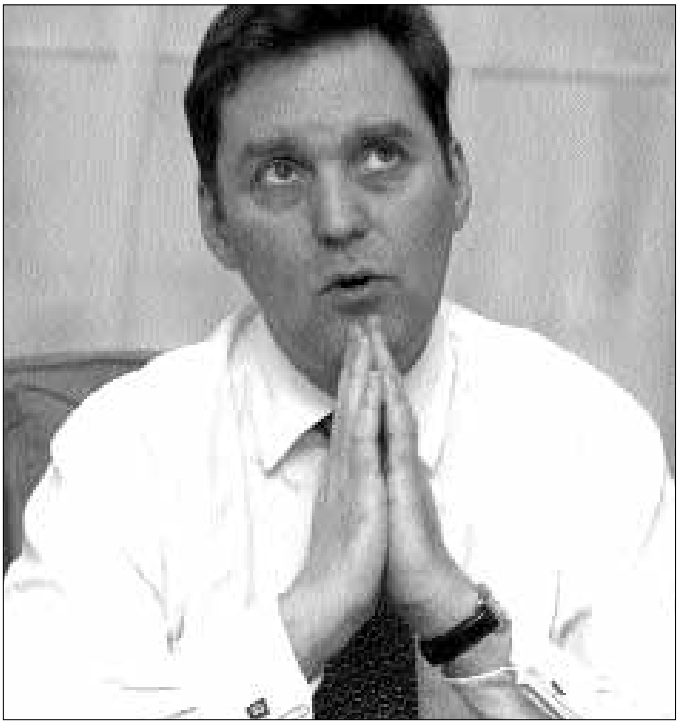
As the years passed and members grew older, money would start to be withdrawn from the mutual funds, but in the short run there will be a major growth in funding for the development of health care services.

If we are to catch up with other European countries we need just such an immediate boost in funding. An arrangement based on mutually owned PCTs would be voluntary and potentially create the sense of genuine social solidarity always promised by the NHS but never achieved.

Independent Hospitals

There is now a cross-spectrum consensus in favour of establishing self-governing hospitals and the Government is likely to create two or three independent hospitals within the next year or two.

In one corner are the champions of a "consumer-led" NHS, who argue hospitals should have a mutual structure to give patients direct representation. In the other corner are the great and the good from the royal colleges and the wider medical profession who expect to dominate foundation hospital boards and run services as they think fit.



Secretary of State for Health, Alan Milburn, wants more private-sector involvement in British health care. *photo: Gill Allen, The Times*

"Secretary of State for Health, Alan Milburn, has been advocating the de-politicisation of hospitals. ... [I]n off-the-record meetings he has been saying he is not worried whether policy wonks categorise hospitals as 'public sector' or 'private sector'."

The difficulty for advocates of a mutual structure is that there are no large-scale working examples to point to, but several structures are already available for non-profit organisations: charities, institutions founded by royal charter, and public benefit corporations.

Historically many hospitals were charities run by trustees. All assets must be used exclusively for charitable purposes and any change of aims requires the permission of the Charity Commission. Unlike mutual organisations, there is no possibility of privatising the assets. Before nationalisation, many hospitals were also founded by royal charter.

Like universities, changes to the royal charter cannot be made without the approval of the Privy Council. Similarly, the assets cannot be privatised and so, if you leave the hospital some money in your will, you can be sure it will not end up in somebody's pocket.

There has been recent interest in creating a new structure, called a public interest company, an idea that draws partly on the American tradition of "public benefit corporations."

Like a charity, it will be unable to alter its mission without permission from an independent regulator, but it will not have the tax breaks enjoyed by charities. It will be able to make trading surpluses, but they will have to be ploughed back for the benefit of the public, not distributed to shareholders. Similarly, assets will have to be used in perpetuity for the benefit of the public.

Market Competition

In choosing the best method of hospital governance the odds are stacked against mutual structures, and the best protection for consumers lies, not in patient representation on the board, but in the freedom to go to a competitor when dissatisfied.

However, the locality-based primary care trust, whose task is to get the best deal for patients from independent hospitals, is tailor-made for mutual ownership and control.

Under Mr. Milburn's guidance, Labour is inching towards a more sustainable health policy. It's true that discussion of alternatives to tax funding still produces intellectual paralysis, but the debate about the supply side is generating some new ideas that will create a blend of consumer empowerment and social solidarity that social-democratic Europe has taken for granted for decades.

Dr. David Green is director of CIVITAS, the Institute for the Study of Civil Society. This essay was abbreviated. The full text is available at http://www.civitas.org.uk. *Dr. Green can be reached at CIVITAS, The Mezzanine, Elizabeth House, 39 York Road, London SE1 7NQ or email* info@civitas.org.uk.

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State Legislative UPDATE

COMPILED AND EDITED BY CONRAD F. MEIER

A MONTHLY REVIEW OF STATE LEGISLATIVE ACTIVITY

While preparing for the November update, I kept running into the numerous convulsions over sharply increasing medical malpractice insurance rates.

In an effort to protect themselves, medical professionals are leaving their practices, leaving a hostile state for a state with reasonable award caps, or flat-out leaving their chosen professions at the peak of their careers. The end result begins to look like the queuing common to single-payer health care plans: fewer doctors for more patients mean less choice and compromised health care for consumers.

Until jurors begin to realize they are shooting themselves in the foot, state legislators are trying to do something. At best, they are scrambling to enact legislation to soothe the malpractice insurance companies in states with demonstrated reputations for outlandish jury awards.

In Nevada, the state legislature was hastily summoned to a special session to address medical malpractice jury awards after Las Vegas' only medical trauma center closed its doors.

New Mexico legislators enacted jury award caps in medical malpractice cases. New Mexico has the worst ratio of claims paid compared to premiums collected. Pennsylvania legislators also approved caps in medical malpractice cases in their regular session this year.

Legislators in West Virginia passed a law requiring an "expert witness" in medical malpractice cases and created a state-run malpractice insurance plan. Only one private medical malpractice insurer remains in West Virginia.

During a special session called by Mississippi Governor Ronnie Musgrove (D), the House passed a bill limiting damages for pain and suffering in medical malpractice cases to $1 million. The Senate passed a measure capping damages at $250,000; the Senate bill applies to civil actions against any business and also limits punitive damages in all lawsuits. The competing bills have created a deadlock in the legislature.

Arizona

Arizona and Mexico signed an agreement to improve health conditions along their shared border. Health problems, including diabetes, tuberculosis, cardiovascular disease, and drug addiction, along the border outpace those in other nearby areas.

Under the arrangement, the two states will receive more than $264,000 from the U.S.-Mexico Border Health Commission next year for a variety of projects. Of that amount, $31,000 will go to create and maintain a health alert network along the border to prevent potential bioterrorist attacks. In addition, the agreement calls for the localities to develop plans to cut obesity and infant mortality rates.

California

Governor Gray Davis (D) signed legislation requiring the state medical board to disclose physician malpractice settlements to the public on its Web site. The law represents a compromise between the California Medical Board, which wanted to make all settlements public, and the California Medical Association, which opposed any disclosure.

Two California Democrats have compromised on the specifics of separate online privacy measures in a move to pass online privacy legislation before this month's election. But Amazon.com and AOL remain opposed to State Assemblyman Joseph Simitian's legislation, saying it unfairly distinguishes online businesses from offline businesses collecting personal information and exempts state agencies, the legislature, and election campaigns from the bill's privacy protections.

Florida

Central Florida hospitals have taken first steps toward HIPAA privacy rule compliance and are already enacting patient privacy safeguards in preparation for the upcoming HIPAA medical privacy rule compliance deadline. Orlando Regional Health System and Florida Hospital will soon stop releasing patient information to the media without patients' written consent and are planning additional privacy measures.

Iowa

Governor Tom Vilsack (D) criticized a plan proposed by gubernatorial candidate and former state Chief of Staff Doug Gross (R) to tighten income eligibility requirements for the state's Medicaid program. Vilsack promised to "fight to make sure it doesn't happen."

Vilsack said the plan would limit Medicaid eligibility to residents with annual incomes less than 100 percent of the federal poverty level, or $8,868 for an individual. The income eligibility requirements for several Iowa Medicaid expansion programs exceed federal eligibility requirements.

Gross has said Vilsack "has driven Iowa's Medicaid program into debt by promising more than it can deliver." Vilsack approved a $61 million bailout of the state's Medicaid program, and the state has estimated a $93 million deficit in the program next year.

Massachusetts

The Walgreen Co. drug store chain said it would not make available to Massachusetts officials detailed information on how much it pays for certain prescription drugs. Lawmakers had called for pharmacies in the state to disclose the information during hearings on a proposed Medicaid reimbursement cut. The pharmacy payment cuts were expected to save the state about $60 million a year. (See related story, "Maine Rx Price Controls Violate Medicaid Law," on page 9.)

Oregon

Voters face a November ballot measure in Oregon that would establish a universal health care system. Under the measure, called the Oregon Comprehensive Health Care Finance Plan, the state would cover the cost of health care for residents through income and payroll taxes. Residents would be taxed up to 8 percent of income and a flat 11.5 employer tax would be levied on business. State residents would not pay premiums, co-payments, deductibles, or out-of-pocket expenses, and the measure would provide coverage for a "full range of physical and mental health services," as well as long-term care and "alternative" treatments.

Officials from Associated Oregon Industries said the payroll and income taxes imposed under the measure would hurt individual taxpayers, cripple Oregon businesses, and cost Oregon jobs.

South Carolina

A Federal District Court judge dismissed a lawsuit filed by the South Carolina and Louisiana state medical societies challenging the constitutionality of the HIPAA privacy rule. In their suit filed last year, the plaintiffs argued the rule was expansive and "overly vague" and violated the separation-of-powers and due process clauses of the Constitution.

Washington

State officials asked HHS for $1 billion in additional Medicaid funds, based on a recalculation of nursing home reimbursements, but reduced their request to $235 million after negotiations with federal officials; HHS has offered the state $70 million. Doug Porter, the state's Medicaid director, said $70 million "isn't enough" and would "certainly not fix the problems we have." Porter added the state may have to make "drastic cuts" in the program without the funds.

Wisconsin

The state prescription drug assistance program for seniors took effect in September and about 42,000 low-income seniors are expected to receive SeniorCare program identification cards. More than 46,000 seniors have applied for the program since July 1. To qualify for the program, a couple must have an annual household income of $28,656 or less.

All participants will pay a $20 enrollment fee and depending on income level, some will be required to pay a $500 annual deductible. Participants also will pay $5 for each generic drug and $15 for each brand-name drug. About 177,000 of the 325,000 eligible Wisconsin seniors will enroll in the program. Approximately 1,100 Wisconsin pharmacies—in addition to 200 pharmacies in neighboring states—have agreed to participate in the plan.

The State Legislative Update is compiled from a wide range of news sources, including the Council for Affordable Health Insurance (CAHI) http://www.cahi.org; *the National Association of Health Underwriters (NAHU)* http://nahu.org; *Bizjournals* http://bizjournals.com; *Stateline* http://stateline.org; *and Lexis/Nexis research.*

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The Galen REPORT

A monthly review of health policy matters

The revolution in consumer-driven health care is indeed taking hold, if the responses to two speeches I gave in October are an indicator.

I spoke in Ocean City to the annual convention of MedChi, the Medical Society of Maryland. Executive director Michael Preston asked me to talk about innovations in consumer-driven health care, including Health Reimbursement Arrangements (HRA) and tax credits for the uninsured.

Then, I traveled to Salt Lake City, where John Nielsen of InterMountain Health Care invited me to keynote the annual meeting of the Utah Health Insurance Association, whose able executive director is Kelly Atkinson.

Doctors and insurers: Clearly two groups with a vested interest in the system, and I wasn't sure how they would react. But in both cases, the majority was remarkably receptive to the changes taking place.

First, the Doctors

They are so angry and demoralized over managed care that they are willing to listen to any new idea that will restore control to them and their patients. They were particularly interested in HRAs, where employers can fund an employee's personal care account to pay for routine medical care, and most often couple it with catastrophic coverage.

Many plans also provide screening and other early-detection tests without charge to the employee to encourage them not to skimp on care. The June 26 IRS ruling allowing money saved in the HRA accounts to roll over tax-free makes these arrangements especially appealing.

"[Doctors] are so angry and demoralized over managed care that they are willing to listen to any new idea that will restore control to them and their patients."

An inevitable consequence of this new spending arrangement is that patients will ask their doctors more questions about cost and will try to get the price down. How do the doctors feel about that? Many agreed that if the patient is a cash-pay customer, it would be possible to cut their rates and still make money because they can avoid paperwork, payment delays, and battles with insurance companies. (See "The SimpleCare Story," *Health Care News*, February 2002.)

Then, the Insurers

They are losing customers, especially small businesses, because premium costs are rising. They want new tools to lure customers back, and they see HRA products as more flexible and affordable and a way to make patients partners rather than adversaries in using care wisely. Small steps can lead to big changes in the system.

Other issues we discussed:

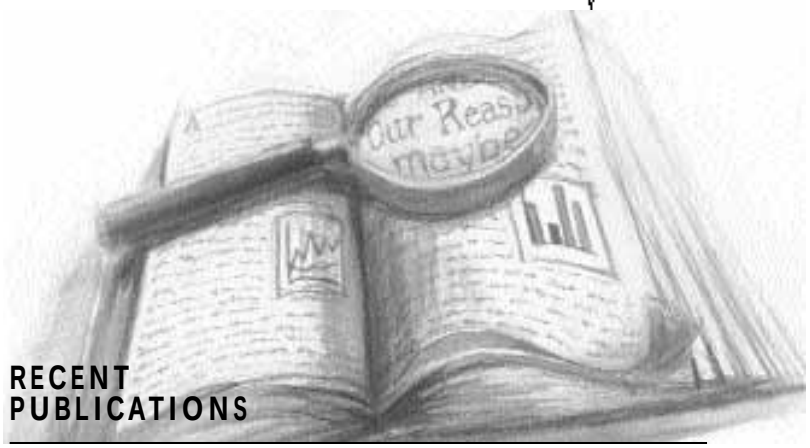
- Health Insurance Flexibility and Accountability Guidelines that are loosening regulatory shackles on states so they can be more creative in their use of Medicaid and SCHIP dollars (a creativity the Senate Finance Committee wants to rein-in).
- The new Independence Initiative from HHS, which would allow disabled people to decide for themselves what they need to achieve greater functionality, not have the government tell them what they can have.
- Refundable tax credits for health insurance, enacted as part of the Trade Act of 2002.

All of these small steps begin to move in the direction of greater consumer choice and empowerment.

Single-payer supporters still made their voices heard in both presentations, some more shrilly than others. They will be a force in the continuing debate, but they were definitely outnumbered.

It's clear that big, top-down changes to the health care system won't fly. Consumer-driven health care ideas are making progress, and may take off sooner than we think. It can't come a moment too soon.

— Grace-Marie Turner



RECENT PUBLICATIONS

Benefits of Individual Health Insurance Plans

eHealthInsurance, 9/30/02

A new eHealthInsurance study examined 30,000 new individual and family plans purchased by its members in the last six months. The company found the average premium for an individual is $155.90 per month and $324.92 per month for a family. The costs have remained stable while employment-based premiums are soaring. The majority of the policies purchased through eHealthInsurance were for comprehensive coverage.

The study also highlights the effects of state guaranteed issue and community rating laws. The average annual premium for a single policyholder in California, which does not have these two expensive insurance regulations, is $1,538, but the average premium in highly regulated New York is more than twice as much, $3,589. The fact sheet provides excellent charts showing breakdowns of premiums by age and state.

Full text of press release: www.ehealthinsurance.com/ehealthinsurance/press/NationalUninsured9.02.html

Full text of fact sheet: www.ehealthinsurance.com/ehealthinsurance/expertcenter/UITxCreditFactSheet_9.25.02.pdf

Why You Can't Buy Insurance

Wall Street Journal editorial, 10/1/02

The *Wall Street Journal* uses the new Census Bureau numbers as a launch pad to detail the dangers of the comprehensive mental health parity bill currently on the front burners in Congress. The Domenici-Wellstone bill would force medium and large businesses to cover 941 mental conditions that would inevitably drive up the cost of health insurance, the *Journal* says. "Do you have the urge to travel without a clear plan, often under an assumed identity?" You may suffer from "dissociative fugue."

This is an invitation to a lifetime of Woody Allen psychotherapy, the *Journal* says. "Refusing to recognize the reality of schizophrenia is a scandal ... but the real scandal in American health insurance ... is that tens of millions of Americans risk financial ruin because of policies that make basic insurance difficult or impossible to buy."

Full text (requires subscription): online.wsj.com/article/0,SB1033433111185654113,00.html?mod=opinion

Give Health Insurance Tax Credit to Workers

Detroit News editorial, 10/1/02

Washington should address the problem of the uninsured by giving individuals tax incentives to purchase health coverage, the *Detroit News* writes. The editorial says the Achilles heel of employment-based insurance is its lack of portability.

"Under this system, employees do not own or control their benefits and therefore cannot carry them from job to job or maintain their coverage during periods of unemployment. ... The best way of helping these workers would be by revamping the federal tax code to give workers tax incentives to purchase their own health coverage. This is a complicated, long-term project that will require considerable political will."

Full text: www.detnews.com/2002/editorial/0210/01/a08-601027.htm

FDA Needs a Dose of Reform

Robert Goldberg

Wall Street Journal, 9/30/02

Robert Goldberg of the Manhattan Institute writes that Dr. Mark McClellan's nomination to head the Food and Drug Administration (FDA) "couldn't have come soon enough. ... The agency, whose charter was originally to protect people from snake oils and medicine men, has become a bureaucracy that 'protects' people from the drugs that can save their lives."

Goldberg documents how "careless scientific reasoning" and "outright bureaucratic incompetence" keep promising new drugs out of the hands of patients, with a documented cost of lives. Goldberg recommends the FDA set up an advisory system to consult practicing doctors, scientists, and statisticians rather than "policy elites" who distrust innovation.

Full text: www.manhattan-institute.org/html/medical_progress.htm *(link on left side of the page)*

Material for this report is provided by The Galen Institute, P.O. Box 19080, Alexandria, VA 22320, http://www.galen.org. *Grace-Marie Turner is president. This report was produced by Elizabeth Lamirand, who can be reached at 703/299-9550, and edited by Conrad F. Meier, managing editor of* Health Care News.

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My TURN

BY CONRAD MEIER - MANAGING EDITOR

Health Care Inflation 101

On September 21, 2002 *USA Today* writers attempted to explain double-digit health care inflation. The news story (and I'm being generous here) was headlined: "Finger Pointers Can't Settle On Who's to Blame for Health Costs."

As lead finger pointer, *USA Today* pointed to anything that moved, everything that smacked of free-market enterprise, and everyone connected in some manner to health care delivery and health insurance.

In fairness to the *USA Today* reporters, they admit they can't settle on who is to blame. And was I relieved. I thought momentarily they were about to blame me for having a $28,000 hip replacement that threw the whole system out of sync.

What's out of Sync?

While the media play up inflation news and the latest census report on the number of uninsured Americans, most people, including those who would report on our health care system, fail to understand how excessive government mandates and overbearing regulations on health care practitioners and health insurance companies play a major role in health care inflation.

PricewaterhouseCoopers (PwC) released a study in May 2001 projecting an overall premium increase of 13.7 percent for 2002. PwC attributes 15 percent of that increase to government mandates and regulations, 7 percent to litigation, and 5 percent to fraud and abuse. (As an aside, part of the problem is this information barely made page eight in most daily newspapers, the *Wall Street Journal* being the exception.)

Taken together, mandates, litigation, and abuse account for 27 percent of the increase in health care costs in this country, more than any other factor. Other lesser factors leading to health care inflation include new pharmaceuticals and medical devices (22 percent), rising hospital expenses (18 percent), general inflation (18 percent), and increased consumer demand by a growing senior citizen population (15 percent).

"If finger pointing is still of any value, point in the direction of Congress and state legislatures. It is there we can find the critters who fuel health care inflation."

The PwC study also reveals how 15 percent of the current $67 billion increase in health spending during 2001 is directly attributable to laws passed by legislators.

Cost-Shifting

Over the last 40 years, 1,500 unfunded insurance mandates zipped through state legislatures because politicians saw them as an easy way to garner constituents' votes without having to raise state taxes or spend more on public health issues. Now, that massive cost-shift has come back to haunt us.

Mandates require health insurance benefits to include everything from pastoral counseling, in vitro fertilization, and sperm bank deposits to wigs for cancer patients. When combined with procedural mandates like "community rating" (insurers may not base premium cost on risk factors like life-style choices) and "guaranteed issue" (wait until you get sick to buy health insurance), these become the ingredients for an inflationary cocktail.

According to online insurance broker eHealthInsurance, guaranteed issue and community rating laws have a dramatic—and negative—effect on insurance premiums.

California has neither mandate. The average annual premium for a single policyholder in the Golden State is $1,538. By contrast, single policyholders in New York pay $3,589—more than twice as much—for their annual insurance premiums. New York imposes both community rating and guaranteed issue on policies sold in that state.

If finger pointing is still of any value, point in the direction of Congress and state legislatures. It is there we can find the critters who fuel health care inflation.

Political Snake Oil

In an effort to solve health care problems, we seem all too willing to accept the judgment of politicians as a substitute for the judgment of buyers and sellers in a free marketplace.

I, for one, would not select an insurance benefit to pay for a toupee, in vitro fertilization, sperm-bank deposits, or mental health care on parity with any physical illness. Yet I pay for them anyway because politicians have made that decision for me by passing health care mandates. The political snake-oil cure for our health care system has done little to help ... and an awful lot to raise the cost of health insurance beyond the reach of an ever-growing number of citizens.

The decision to pay for insurance that covers treatment for baldness, low sperm count, or any other of many special-interest health issues should be made by individuals themselves, not by state or federal government agents.

Most actuaries, insurers, and health policy economists agree virtually all mandates increase the cost of health insurance. In addition to the PwC data and the new eHealthInsurance study, their opinions are further supported by Congressional Budget Office (CBO) figures, which show every 1 percent rise in premium price forces 200,000 people to drop private health insurance.

While some would call the uninsured rate a national crisis and demand even more government intervention, I suggest it is a scandal and demand less of the government intervention that caused it.

The real issue isn't that some people don't have a health insurance policy, but rather that millions of Americans can't afford the cost of insurance because of the mandates imposed by their representatives in government.

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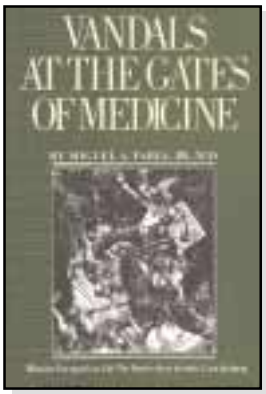
The Classics are Still Available



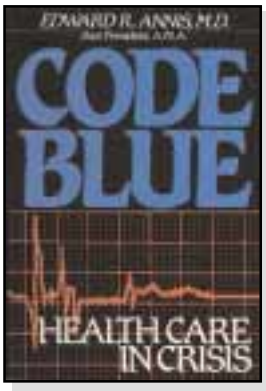
Vandals At The Gates of Medicine

Historic Perspectives on The Battle Over Health Care Reform

Miguel A. Faria, Jr., M.D.

Miguel A. Faria, Jr., M.D. provides compelling arguments that answers to the dilemma of health care reform reside on the pages of history. This fascinating book draws parallels between the past and the present, from a time when the fine line separating myth and history was blurred and indistinguishable to the clearly troubled present.

(403 pp., 1995, Illustrations, Bibliography, Index, ISBN: 0-9641077-0-8, $41.95)



Code Blue

Health Care In Crisis

Edward R. Annis, M.D.

Sold Out!

What the press doesn't tell the public—but Dr. Annis does—is that health care problems have a "Made in Washington" label. Code Blue shows how with "minimal changes in our tax laws, Medisave accounts would empower the patient by breaking the tie between job and health insurance and even would allow the gradual phasing out of Medicare."

(278 pp., 1993, Index, ISBN: 0-89526-515-X, $21.95)

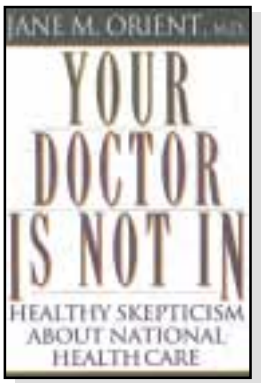
Medical Warrior

Fighting Corporate Socialized Medicine

Miguel A. Faria, Jr., M.D.

In this book of essays, Dr. Faria, argues that managed care and HMOs are not "free market" alternatives, but rather an unholy partnership of government and corporate interests seeking monopolistic government protection to eliminate competition while changing the ethics of medicine from a Hippocratic ethic to a false corporate morality. *Medical Warrior* offers workable solutions to restore medicine to its rightful place.

(207 pp., 1997, Selected Bibliography, Index, ISBN: 0-9641077-2-4, $23.95)

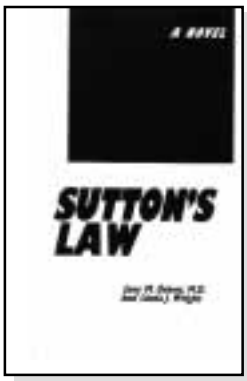


Your Doctor Is Not In

Jane M. Orient, M.D.

In this provocative book, a brilliant, committed physician, a leader in medicine argues for solutions to the crisis in medicine that are bold, thoughtful, and fundamentally opposed to those being widely touted today—including "managed care" systems. From her perspective, there is already too much government involvement in medicine, too much regulation, too much insurance—which is actually prepayment in disguise. These are the root causes of the accelerating rise in fees and costs, the neglect of patients, and stagnation in the science of medicine itself. This book is certain to add fresh energy to the debate over the quality and availability of medical care in America.

(276 pp., 1994, Index, ISBN: 0-517-59011-5, $23.00)



Sutton's Law

Jane M. Orient, M.D. and Linda J. Wright

Sutton's Law is a "frightening realistic novel about where managed care might very well lead us...A mix of medicine, mystery, murder, and intrigue with a little high finance, drugs, and romance—*Sutton's Law* ultimately is about greed and simple justice."

(299 pp., 1997, ISBN: 0-9641077-1-6, $21.95)

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